Safety in European community product regulation

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THE SAFETY REGULATION OF CONSUMER PRODUCTS IN EUROPE

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ABSTRACT OF THESIS

This thesis examines the European Community's legislation that regulates the safety of consumer products, and the extent to which such legislation aims and succeeds at achieving the safety in use of such products. The specific sectors covered are medicinal products, products covered by "New Approach" Directives, cosmetics, biocides, tobacco products, and consumer products covered by the General Product Safety Directive.

First, the constitutional legal basis of the legislation is examined in Community law. Overviews are then given of the legislative schemes employed in the various families of legislation, which concludes that various techniques that may be expected to contribute to safety are found in different laws.

A detailed examination follows of the extent to which the particular techniques (covering pre-marketing assessment, provision of information, control of the manufacturing environment, post-marketing obligations on producers and authorities, and obligations on distributors and users) are found in the various families of legislation. The extent to which individual product laws contain particular obligations is measured against theoretically complete frameworks of obligations which are suggested for the most important techniques. Gaps in the existing legal obligations are noted.

There is then an analysis of the legal tests that are included in the legislation for the level of safety which products must satisfy, pre- and post-marketing, noting differences between each product sector, and between the pre- and post-marketing situations. The meaning of "safety" is considered, as are the multiple actors having responsibility for achieving product safety, and how they inter-relate in a system of supranational governance. Finally, it is found that the potential subjectivity that is inherent in perceptions and decisions of what is acceptably safe can differ considerably, but that plurality of views (incommensurability) can be accommodated within a system that contains certain safeguards: the extent to which such features are present is found.

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ABBREVIATIONS

ADR	Adverse drug reaction
AE	Adverse event
CE marking	The marking of a product with "CE", in the approved configuration, which signifies that the product satisfies the essential requirements of a New Approach technical Directive
CEN	The European Standards Association
CENELEC	The European Association for Electrical Standards
Commission	The European Commission
Community	The European Community
Competent authority	A regulatory authority designated by a Member State
Court of Justice	The Court of Justice of the European Communities
Declaration of conformity	A manufacturer's declaration that a product conforms with the essential requirements of a New Approach Directive
ECOSA	European Consumer Safety Association
EEA	European Economic Area
EFTA	European Free Trade Association
EHLASS	Community's system for collection of information on safety incidents reported with consumer products
EMC	Electromagnetic Compatibility
EMEA	European Agency for the Evaluation of Medicinal products
Essential requirements	The scientific and technical requirements with which a product must comply, specified in a New Approach Directive
GPSD	Directives 92/59/EEC and/or its successor 2001/95/EC on general product safety
IEC	International Electrotechnical Commission
ISO	International Standards Organisation
LVD	Low Voltage Equipment Directive, 73/23/EEC, amended by 93/68/EEC

Member State	A Member State of the European Community
New Approach	The Community series of regulatory legislation specified in Council Resolution of 7 may 1985 on a new approach to technical harmonisation and standards, OJ 1985 No C 136/1, 4.6.85, supplemented by the Council Resolution of 21 December 1989 on a global approach to conformity assessment, OJ 1989 No C 10/1, 16.1.90.
Notified Body	A technical testing and certification organisation which has been approved to have "notified body" status as an official certification organisation in relation to a New Approach Directive and is so listed by the Commission in the Official Journal of the European Communities.
Pharmacovigilance	The post-marketing system comprising surveillance and reporting of adverse drug reactions associated with medicinal products.
PPE	Personal protective equipment
PROSAFE	The informal association of Consumer Safety Enforcement Officials of Europe
RAPEX	Community authorities' notification system for rapid alerts on consumer products presenting serious risks
SmPC	Summary of Product Characteristics of a medicinal product

1. INTRODUCTION

This thesis analyses whether European Community[1] regulatory legislation can be expected to deliver, and succeeds in delivering, product safety. It examines whether the legal basis of the legislation is coherent, what mechanisms are deployed in the legislation, whether the mechanisms that are employed in the legislation can be expected to be effective, how we could test whether the regulatory system is effective, whether we can apply such tests, and whether we know if the system does (efficiently) deliver safety.

It is apparent that significant and sometimes complex regulatory mechanisms are imposed on a range of product sectors. Legislative requirements impose significant obligations on manufacturers and competent authorities, as sometimes other actors such as distributors or even users.

Various matters are not covered in this analysis: it is not an historical or comparative account of the development of the legislation; it takes the legislation as it exists, divided into particular sectors, and does not analyse any possible rationale for such divisions, nor borderline or classification issues that arise; and it does not cover the part played by product liability law. The legislation that is examined is that of the European Community, at Community level and this thesis does not analyse whether transposition into the law of Member States has been correctly achieved, nor matters related to enforcement, in particular the important issue of how well Member States succeed in fulfilling their responsibilities over enforcement. The thesis also does not cover the interesting issues of comparison with regulatory systems in other jurisdictions, notably the United States of America, where there is a long history of product regulation and extensive academic analysis, save that a small number of important books are noted. Similarly, this analysis does not cover any product regulation that existed under the national laws of Community Member States before Community provisions were introduced, or the effect that Community provisions may have had on national provisions. The focus is simply on the Community legislation *per se*.

The analysis is restricted to the legislation regulating the main consumer product sectors, namely medicinal products, the wide range of products regulated under the Community's 1985 "New Approach", cosmetics, biocides, tobacco and general consumer products falling under Directive 2001/95/EEC. This excludes certain related sectors for reasons of space, such as motor vehicles, foodstuffs, and aerospace products, and other areas of law which contain similar mechanisms, such as health and safety in the workplace and environmental control.

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[1] The Directives fall under the EC Treaty, as amended, not the Treaty on European Union, and the relevant law will be referred to as Community Law.

The analysis proceeds as follows. Part One considers the legal and constitutional basis of the legislation, some important court decisions, and then the main sectoral and horizontal legislation. It first seeks to examine what the legal and constitutional basis of the legislation is, and whether this is coherent. The starting point is to examine the relevant provisions of the EC Treaty that provide jurisdiction for the various individual Community instruments are found.

All of the legislation considered here is included in the examination on the basis that its primary socio-legal function is in fact the regulation of the *safety* of the human beings who may come into contact with the products concerned. The product sectors that are considered (including medicines, medical devices, toys, electrical and electronic products, cosmetics, biocides, tobacco, furniture, clothing) are selected on the basis that the products concerned are essentially products that are intended for and used by individual consumers. It is true that some sectors that are included may also contain products that are, sometimes or primarily, also used in workplace situations, and so subject to the separate regulatory regime that applies to workplace products by imposing obligations on employers. But products that are used in the workplace, such as machinery and lifts, are also used to a greater or lesser extent by consumers and, in addition, the product regulatory regimes that apply make no distinction between workplace and consumer usage.

It may be expected that legislation that is intended essentially to regulate product safety should have as its fundamental rationale and legal objective the achievement of product safety. However, it will be seen that the jurisdictional basis of the legislation rests squarely on the facilitation of trade within the internal market of the Community. Thus, unless there is evidence that there are barriers to trade caused by national provisions dealing with a specific area of product regulation, the Community does not possess jurisdiction to enact legislation on such an area. Conversely, Community legislation regulating products can only validly be based on ensuring that such rules as apply remove any national barriers to trade which may previously have existed and provide a harmonised basis for trade in the relevant products.

It will also be seen that although the Treaty includes references to the goals of consumer protection and of the protection of public health, these are included as aspirational rather than legally binding goals, and therefore have little legal significance. However, there are some signs from decisions of the Court of Justice that consumer protection issues may be assuming greater significance that the strict, formal parameters of trade in some situations. The case law of the Court of Justice does, however, clearly establish the limitations of Community competence, so that where total harmonisation provisions do not exist at Community level, Member States retain legal competence to set policy on product safety issues subject to not transgressing Community provisions such as Articles 28 and 29 of the Treaty, and although the Court will construe the Article 30 (public health)

exemption from such requirements strictly, Member States retain significant discretion in setting national public health policy.

Part One continues with three chapters (Four to Six) that analyse the general provisions of the various pieces of legislations that apply to the selected product sectors. The essential purpose is to identify the control mechanisms that are adopted in the legislation which are intended to achieve the safety in use of the products which are covered. Part One will identify that there are two central opposing contrasts to be found as regards the individual mechanisms: whether an individual mechanism applies in the pre- or post-marketing situation, and whether the obligation applies to the manufacturer (or sometimes another commercial entity) or to a competent authority (or other quasi-regulator).

Analysis of the techniques so identified will raise for consideration a sequence of questions about such mechanisms. First, what is the nature and purpose of each technique used? Secondly, when is each individual mechanisms applied? Thirdly, to whom does it apply? Fourthly, how effective is it likely to be? Part Two examines these issues, by considering each technique in turn, taking the individual techniques in the chronological sequence of product design and manufacture. In relation to each of the major pre- and post-marketing control techniques, a theoretical sequence of relevant steps and obligations will be proposed, and the extent to which each theoretical step is in fact found in each of the vertical and horizontal families of legislation will then be identified. This comparative exercise will, firstly, reveal the extent to which particular control mechanisms have been deployed in different product sectors (and where the gaps are) and, secondly, enable a "benchmarking" exercise to be undertaken of best practice in relation to individual mechanisms and their legal modes of expression. This benchmarking exercise should be of value in view of the fact that although the different items of legislation have many similarities, not least in being written in the same legislative style of all Community legislation, the techniques adopted in each product sector or family which have the objective of ensuring product safety have not been developed as part of a coherent whole.

Part Three widens the analysis by considering various general theoretical issues. Chapter 17 considers the state of academic analysis of regulatory systems and how they work. Much of this relates to the economic regulation of markets but useful conclusions can be drawn for the regulation of social goals such as safety. A particular question is why different regulatory mechanisms should be adopted for different product sectors: the general conclusion is that variations in the public perceptions of risk posed by differing products is a significant factor.

It is also found that there is considerable scope for competing values on safety, risk and individual decisions. The main interest groups whose views need to be accommodated are commercial

operators, consumers, regulators and politicians. The mechanisms within which each group operates and the institutional context in which the various groups inter-relate are examined in chapter 18. The constitutional legitimacy of existing legal mechanisms is tested against criteria and particular deficits are noted in areas that include democratic accountability, expertise, and efficiency.

It is assumed in Parts One and Two that the meaning of "safety" is understood in relation to products: chapter 19 analyses the meaning of this concept. It is found that there is no legal norm of "safety" and that the Community policy of ensuring "a high level of protection" of health and safety is political and aspirational but incoherent as a legal test for the marketing of products. A test that is adopted in practice, notably for medicines, uses risk/benefit criteria, but this similarly begs a series of questions about what individual aspects are to be included, the weight to be given to each aspect, and how the overall judgment is to be made. A possible resolution to the problem is to adopt an empirical approach, but this would require agreement on assigning values to comprehensive risks and benefits, and on what levels of risk assessments are acceptable.

A consequence of the absence of empirical data is that current systems are incapable of identifying the extent to which either the regulatory system or its individual mechanisms deliver safety, or operate efficiently. Nevertheless, the regulatory regime continues to operate. A legal system is able to operate on the basis of plurality of individual views on detailed matters within a framework of broad agreement on principles, given transparency, accountability to stakeholders and the opportunity for vigorous open debate on issues. Given that finding, those criteria are used to test the robustness of the regulatory systems, and improvements are suggested. Finally, suggestions for the future are put forward.

The legislation is considered as at 31 August 2003.

PART I

2. DESCRIPTION OF THE MAIN REGULATORY SYSTEMS AT COMMUNITY LEVEL

This Part sets the scene by outlining the essential structure of the Community's product regulatory legislation. Chapter Three examines the constitutional basis of the legislation under Community law. This is important because the Community only has competence to legislate to the extent permitted by its Member States and specified in the EC Treaty. The examination will need to identify the jurisdictional basis of the legislation, and whether the legislation has been properly based. Although the Treaty includes references to consumer protection and protection of public health, it will be found that these do not form the constitutional basis of the relevant legislation, which is founded on the goal of the establishment and functioning of the Community's internal market. Thus, the Community only has power to legislate where there are distortions in or barriers to trade within the market, and the legislation remains to be interpreted essentially in accordance with this power. This finding raises the issue of whether legislation whose real primary function is to ensure human safety should legally be placed on a different basis: this is a major issue that will be considered at the conclusion of this thesis.

The Treaty does, however, specify that its legislation in the fields of consumer protection, public health and the internal market will seek to provide a "high level of protection" of health and safety for citizens. Examination of the significance of this goal reveals its limitations both as legal force and political policy. It raises the issue of what level of safety society intends to specify as acceptable, and this issue will be discussed further in Part Three.

Chapters Four to Six examine the basic structures of the various product regulatory regimes that are the subject of this thesis. Community law regulates products by applying a series of different structural approaches and different control techniques to different product sectors. At first sight, each product sector appears to have a distinct structure and to deploy different techniques. Yet closer scrutiny reveals a number of similarities. Medicinal products are subject to grant by the authorities of various authorisations after satisfaction of extensive pre-marketing requirements, and they also have post-marketing vigilance requirements. Biocides are also subject to authorisations. The cosmetics system is based on lists of substances drawn up by experts that are approved or banned. In practice, chemical substances that are frequently used in medicinal products, biocides or cosmetics usually have their chemical composition prescribed in official formulae, such as a pharmacopoeial standard, which is intended to standardise not only the properties and effects of a

specified quantity of a given substance but often also its method of preparation. Tobacco control is also based on control of ingredients, so that standard products are produced that have predictable quantities of the substances which are given off when they are used and are associated with harm, namely tar and nicotine.

The above mechanisms apply to products which are primarily chemical substances or naturally occurring substances that are used chemically or biochemically. In contrast, products that comprise engineered materials are subject to different types of controls on their engineering design and production. The Community's New Approach system requires the manufacturer to certify conformity with prescribed essential requirements.

Regulation of all of the above systems is based on different regulatory regime which is specific for a particular product sector – medicinal products, biocides, cosmetics, tobacco, and the various sectors covered by the New Approach (which are listed in Table 2). A further approach acts as a long-stop for all consumer products which are not covered by a specific vertical regime, on a "horizontal" basis. The focus of the GPSD requirements is on provision of information and, from 2004, post-marketing systems. A sophisticated post-marketing system is also found in the medicinal product sector (the pharmacovigilance system), having been established during the 1990s, and a medical devices vigilance system is more recent and less legally sophisticated but has a number of similarities.

All of the different regulatory regimes require labelling information to be given to users, which includes warnings on particular hazards, and this is a notable feature of tobacco products, where mandated warnings of specified size and content are prescribed.

The outcome of the analysis of chapters Four to Six will be identification of the list of individual control techniques which are used in the various sectoral and horizontal regimes. That will enable an analysis to be undertaken in Part Two of the nature and purpose of each regulatory technique in turn.

One possible approach to safety issues is in empirical terms. However, statistics are difficult to find in this area. Some data are assembled in Appendices 2 – 4, but it becomes increasingly clear, as discussed further in chapter 19, that evaluating the data is more a matter of perception than objectivity.

3. THE LIMITS ON THE COMMUNITY'S JURISDICTIONAL COMPETENCE IN PRODUCT SAFETY LEGISLATION

What is the basis of Community competence?

In seeking to understand the nature of Community legislation on product regulation, the first issue to be established is the basis of jurisdictional competence that the Community possesses in relation to legislating in the field of product regulation. For present purposes, it is assumed that the rights of Member States to legislate on this subject are, subject to any national constitutional parameters, unlimited save as provided for by the EC Treaty.[2] It is, however, well established that the Community only has the jurisdictional competence delegated to it by the Member States as set out in the EC Treaty. What, therefore, is the foundation upon which product regulation may be based, and what are its limits?

The internal market parameter

The basis upon which the Community possesses competence to legislate in relation to product regulation is based almost exclusively not upon a policy of consumer protection or the achievement of a level of safety but upon the facilitation of trade, in particular the free movement of goods,[3] in the context of the Community's internal market.[4] Almost[5] all of the measures[6] that are within the scope of the current enquiry were introduced under Article 95 (formerly 100a) of the Treaty, which provides that the Community has power, in the achievement of the objective of progressively establishing the internal market,[7] to adopt measures

> "for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market."

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2 World Trade Organisation or other bilateral treaties are outside the scope of this thesis.

3 There are many works dealing with this topic: see particularly P Craig and G de Burca (eds), *The Evolution of EU Law* (Oxford, 1999); K Armstrong and S Butler, *The governance of the Single European Market* (Manchester, 1998), which notes that the single market project was essentially an economics-driven programme for regulatory reconstruction within the European area, regulating market access and competitive behaviour.

4 The internal market is defined in Article 14 EC as comprising an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaty.

5 Article 100a EC came into effect in 1985 and pre-dated almost all of the legislation considered here. Those Directives that preceded Article 100a can either be seen in effect to have the same general constitutional parameters, aims and approach (such as those dealing with medicinal products, as discussed below) or to have been subsequently amended so as to come under Article 100a (such as Directive 2003/15/EC on cosmetic products, and Directive 73/23/EC on low voltage equipment, which was brought within the "new approach", and therefore Article 100a, followed by Directive 93/68/EEC).

6 In other words, Community Directives and, sometimes, Regulations.

7 Specified, under that part of the Treaty headed "Principles", by Article 14 EC.

Thus, two pre-conditions are necessary in order to justify a Community measure under this provision. There must, first, be an *existing* corpus of national provisions that differ sufficiently so as to require approximation. Secondly, the measures that are adopted *must have as their object the establishment and functioning of the internal market.*

The Court of Justice has struck down Community measures that do not have proper foundation. For example, in 2000 the Court of Justice struck down a Directive on tobacco advertising on the basis that the measure was in truth one of public health policy rather than market-building.[8] The Court held that Article 95 does not contain a general power to regulate the internal market, and that, in accordance with the Community principle of specific attribution of powers,[9] measures based on Article 95 must make an actual contribution towards the establishment and functioning of the internal market. In the context of product regulation, therefore, a measure must actually contribute towards eliminating obstacles to the free movement of goods or to removing appreciable distortions of competition.

The strict approach to jurisdictional issues that has been adopted by the Court of Justice can be seen in its decision upholding a Directive on tobacco advertising which was promulgated after the above case, and contrasts with it. The two cases illuminate the fine distinctions that are drawn over the jurisdictional inter-relation of competing principles, in particular between those of public health and the functioning of the internal market. In the second decision, the Court held that if a Community act has a twofold purpose or twofold component and if one of these is identifiable as main or predominant, whereas the other is merely incidental, the act must be founded on the sole legal basis required for the main or predominant purpose or component.[10] Exceptionally, if an act simultaneously pursues a number of objectives that are "indisociably"[11] linked without one being secondary or indirect in relation to the other, such an act may be founded on the various corresponding legal bases.[12] Adopting the former basis, the Court of Justice held that Article 95 is the proper basis for Directive 2001/37/EC on the manufacture, presentation and sale of tobacco products,[13] since it is intended to improve the conditions for the establishment and functioning of the internal market, and the Community legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices made, which

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8 Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8419.

9 Article 5 EC provides: "The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives to it therein."

10 See Case C-42/97 *Parliament v Council* [1999] ECR I-869, paras 39 and 40; Case C-36/98 *Spain v Council* [[2001] ECR I-779, para 58; Case C-491/01 *British American Tobacco (Investments) Ltd* [2002] ECR I-11453, para 94.

11 This is the word used in the report of the judgment but "insolubly" makes more sense.

12 Opinion 2/00 [2001] ECR I-9713, para 23.

13 Discussed further at chapter 6.

include factors such as the increased importance given to the social and political aspects of the anti-smoking campaign .[14]

However, in rare cases the Court of Justice has "emphasised that in principle the requirements of the protection of public health must unquestionably be given precedence over economic considerations".[15] This approach is difficult to rationalise on the basis of the Treaty provisions quoted above. However, it can be noted that there have been occasions when the Court of Justice has expressly taken public safety into account in a less controversial context, such as in deciding that the definition of what constitutes a product type for the purposes of coming under a Directive should be given a broad interpretation.[16] A further observation is that the courts have limited the scope of judicial review in cases such as those involving medicinal products that involve complex assessments, by permitting the competent authorities a broad discretion,[17] on the basis that the definition of what constitutes a medicinal product can be far from straightforward and the competent authorities must be allowed a margin of appreciation in making a determination in cases on the borderline.[18]

The Court of Justice has also relied on the fact that since different vertical product regulatory systems that are based on Article 95 do include, as a subsidiary aim, the protection of public health, that policy aim is decisive in deciding a borderline issue, namely that one system (for medicinal products) which is more rigorous than another (for cosmetics) will apply to a product that would otherwise fall under the definition of either system, "in view of the particular dangers which the

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14 Case C-491/01, above, paras 58–98.

15 Order of the Court of Justice in Case C-180/96 *United Kingdom v Commission* [1996] ECR I-3903, para 93; judgment in Case C-183/95 *Affish v Rijksdienst Keuring Vee en Vlees* [1997] ECR I-4315, para 43; Order of the Court of First Instance in Case T-136/95 *Industria del Frio Auxiliar Conservera v Commission* [1998] ECR II-3301, para 58; and Order of the President of the Court of First Instance in Case T-70/99 R *Alpharma v Commission* [1999] ECR II-2027, paragraph 152.

16 Case C-112/89, *The Upjohn Company and Upjohn NV v Farzoo Inc and JAWMJ Kortmann*, [1991] ECR I-1703; the definition of a medicine under Article 1(2) of Directive 65/65/EEC (now 2001/83/EC) must be given a sufficiently broad interpretation to cover all substances capable of having an effect on the actual functioning of the body.

17 Case C-120/97 *Upjohn Ltd v The Licensing Authority established by the Medicines Act 1968 and others* [1999] ECR I-00223: the court may not substitute its assessment for that of the authority and must restrict itself to examining the accuracy of the findings of fact and law made by the authority and to verifying, in particular, that the action taken by the authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion; Case C-112/89, supra; Case C-227/82 *Van Bennekom* [1983] ECR I-3883; see also *In the Matter of Organon Laboratories Ltd etc; R v Medicines Commission and The Department of Health and Social Security ex p Organon Laboratories Ltd*, Divisional Court transcript CO/1738/88, 17 February 1989, per Glidewell LJ. Contrast cases where the assessment is not complex (such as one of the safety, efficacy or quality of a medicinal product), in which case the scope of judicial review is not so restricted; Case T-179-00 *A Menarini-Industrie Farmaceutische Riunite Srl and the European Federation of Pharmaceutical Industries and Associations v Commission of the European Communities* [2002] ECR II-02879.

18 *R v Medicines Control Agency ex p Pharma Nord (UK) Ltd*, [1998] 3 CMLR 109, CA, per Lord Woolf MR.

former may present to public health and [which] cosmetic products generally do not".[19] In placing public safety as the paramount consideration in this way, it is arguable that such an approach is in fact counter to the paramount principle of the free movement of goods, since making a product subject to more rather than less rigorous regulatory controls where there is a choice between them does impose a barrier to trade, but this approach is consistent with Article 95.3 EC and few would argue with it.

Weatherill has pointed to the fact that a wide range of measures have been enacted under Article 95, which include various provisions that adopt a broad and questionable constitutional basis, but have survived unchallenged because of Member States' unanimity in supporting them on wider policy grounds.[20] A question that arises, therefore, is whether all of the provisions in the extensive corpus of product regulation are constitutionally invalid. A particular candidate for scrutiny in this respect would be the post-marketing requirements that are found in, for example, Directive 2001/95/EC on general product safety. A strong argument can be made that a number of the post-marketing requirements[21] imposed by that Directive on commercial enterprises and competent authorities do not contribute towards eliminating obstacles to the free movement of goods or to removing appreciable distortions of competition, although the Court has held that powers delegated to the Commission under Article 9 of Directive 2001/95/EC are validly based on Article 95.[22]

The goal of achieving a "high level of protection" in safety, public health and consumer protection

Although the free movement of goods within the internal market is the primary policy consideration for the relevant legislation, various provisions of the Treaty specify the need for "a high level of protection" in matters of safety, health, public health and consumer protection. The requirement occurs most notably in Article 95.3 (formerly 100a), which requires that for all measures based on Article 95 that concern health, safety, environmental protection and consumer protection, the Commission "will take as a base level a high level of protection" of health and safety, taking account in particular of any new development based on scientific facts.

Various interesting points arise from Article 95.3. It is worded as an instruction to the

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19 Case C-60/89, *Criminal proceedings against Jean Monteil and Daniel Samanni*, [1991] CER I-1547 at para 16.

20 S Weatherill, "The Commission's Options for Developing EC Consumer Protection and Contract Law: Assessing the Constitutional Basis" [2002] EBLR 497. See also P J Slot, "A Contribution to the Constitutional Debate in the Light of the Tobacco Judgment" [2002] ELR 3.

21 Discussed in chs 11 and 12.

22 Case C-359/92, *Re The Product Safety Directive: Germany v E.U. Council* [1995] CMLR 413.

Commission,[23] that the Commission shall take a high level of protection as a base level in its proposals. This does not necessarily mean that such measures will in fact provide or ensure a high level of protection. Indeed, no consequences flow if the instruction is disobeyed or unfulfilled. Article 95.3 continues that the European Parliament and Council will "seek to achieve this objective", which presumably means that they, for their part, will seek to pass only measures that do take a high level of protection as a base level. But there is much between taking a particular policy in initial proposals, in seeking to achieve that policy, and in being bound to pass legislation that in fact has and retains the same objective. Thus, these provisions of Article 95 are procedural and aspirational, and difficult to enforce as binding policy, even though they have been described as constituting the development of an European *doctrine* in the field of safety, health, and consumer protection.[24]

The legislation enacted under Article 95 that concerns health, safety, environmental protection and consumer protection, including the GPSD and all technical Directives, invariably includes in its recitals a statement that the legislation is enacted with a view to ensuring "a high level of protection". This is, therefore, both an important policy statement and an aid to the interpretation of the standard of safety set by each of these Directives. Interestingly, the policy considerations set out in some Directives that pre-dated the adoption of Article 100a adopted clearer goals: for example, Directive 73/23/EEC on low voltage products aimed at harmonisation of national measures "designed to ensure safety" and Directive 76/768/EEC on cosmetics referred to the safeguarding of public health.

One might expect that fundamental rationales and goals for extensive legislation would be based on extensive, or at least clear, statements of the theoretical and policy rationales that underlie and justify them. Economic writing justifies the creation of a single market of sufficient size with no barriers to trade or distortions in competition.[25] However, one searches in vain for literature which debates or justifies the selection of a high level of protection of health and safety as a fundamental aim of Community policy, or examines whether it is achieved or, indeed, achievable.

The reference to "a high level of protection" in Article 95 has been criticised by the Economic and Social Committee on two particular grounds.[26] First, as noted above, it only applies to Commission

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23 P Craig and G de Burca, *EU Law: Text, Cases, and Materials* (Oxford, 2ed, 1998) p 1121.

24 J Pelkmans, "The New Approach to Technical Harmonization and Standardization" [1987) 25 *JCMS* 249, 252-3.

25 See M Emerson, M Aujean, M Catinat, P Goybet, A Jacquemin, *The Economics of 1992, The E.C. Commission's Assessment of the Economic Effects of Completing the Internal Market* (Oxford, 1988).

26 Opinion on Consumer Protection and Completion of the Internal Market, Economic and Social Committee, 91/C 339/08, OJ No C 339/16, 31.12.91.

proposals and is not (so the Committee thought, although *pace* article 95.3) explicitly binding on the Council, the Court of Justice or the Member States. Accordingly, the Committee thought that, as defined, the criterion means that consumer protection is weakened in Member States if pre-existing protection happens to exceed that specified by Community legislation. It is unclear to what extent this point is merely theoretical, since examples of the weakening of protection have not been widely put forward in the area of product safety.[27] On the contrary, the legislation discussed here has introduced significant new and innovative provisions in relation to product regulation and safety requirements.

Secondly, it was argued that the best criterion for the consumer would be the highest degree of protection that could be achieved. This view was supported by the European Parliament.[28] It is therefore clear that "a high level of protection" as required by Article 95 is not necessarily the highest level which can be imagined, or which prevails in a Member State which had already made the most progress in adopting consumer protection or technical safety measures in a particular area.

It might be expected that the *absence* of a high level of protection in relation to a particular product sector may have been used as a justification for legislation in the product safety field, but this is nowhere stated to be a rationale or pre-requisite for legislating in that area, with one exception. Only in the GPSD is there a reference to the pre-existing differences in or absence of national laws leading to differences in the level of protection afforded to persons.[29] Even here, however, it is stated not that this is liable to lead to an absence of protection of health and safety but that it is liable to create barriers to trade and distortions of competition.

Relation between product safety and policies on protection of public health and consumer protection

The Treaty establishes two other policies that might be relevant for the present enquiry, namely the protection of public health[30] and consumer protection,[31] but both of these have limited relevance to product safety legislation. The Treaty provision relating to consumer protection policy, as

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27 The general absence in regulatory legislation of references to differences in levels of consumer protection amongst Member States can be contrasted with an explicit reference to a differing degree of protection as justifying Directive 85/374/EEC on product liability (recital 1).

28 Resolution A3 - 0060/92.

29 Directive 92/59/EEC, recital 2; as noted above, see also Directive 85/374/EEC on product liability, recital 1, and the fact that the Court of Justice held that that Directive does not permit Member States to maintain a general system of product liability different from that which it provides for, ie it specifies a mandatory general level of protection rather than a minimum level: Case C-183/00 *Sanchez v Medicina Asturiana SA* [2002] ECR I-03901.

30 Article 152 (ex 129) EC: this was introduced with the Amsterdam amendments of 1996.

31 Article 153, EC.

Weatherill has noted,[32] falls far short of offering a general constitutional mandate to select whatever style of consumer protection policy it regards as appropriate for its aspirations:[33]

> "In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests ... through: (a) measures adopted pursuant to Article 95 in the context of the completion of the internal market; (b) measures which support, supplement and monitor the policy pursued by the Member States."

The same result applies to the provision on public health, which states:

> "A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.
>
> Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating the sources of danger to human health...."

Community documents on public health note that health protection requirements form a constituent part of other Community policies and must be integrated into them.[34] The Council has resolved that Community health action in the field of public health has to be directed towards improving public health, preventing human illness and diseases and obviating sources of danger to human health.[35] The analyses of the state of public health in the Community and the areas for action[36] include emphasis on the roles of tobacco, drug addiction and dependence, but do not mention the safety of products in any other way, save that, in noting that one of the major causes of mortality and/or morbidity is accidents,[37] it is said that the major factors associated with accidents

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32 S Weatherill, op cit, 500. The Court of Justice held in Case C-183/00 *Sanchez v Medicina Asturiana SA, supra,* that Article 153 is worded in the form of an instruction addressed to the Community, and Member States' competence in relation to more stringent protective measures contained in Article 153(5) concerned only measures supporting, supplementing and monitoring the policy pursued by Member States referred to in Article 153(3)(b).

33 Article 153, EC.

34 Report from the Commission to the Council, the European Parliament and the Economic and Social Committee on the integration of health protection requirements in Community policies, COM (95) 196 final, 29.05.1995.

35 Council Conclusions of 26 November 1998 on the future framework for Community action in the field of public health, 98/C 390/01, OJ C No 390/1, 15.12.98; Council Resolution of 8 June 1999 on the future Community action in the field of public health, 1999 C 200/01, OJ C No.200/1, 15.7.1999. For current programmes see Decision No 521/2001/EC of the European Parliament and of the Council of 26 February 2001 extending certain programmes of Community action in the field of public health adopted by Decisions No 645/96/EC, No 647/96/EC, No 102/97/EC, No 1400/97/EC and No 1296/1999/EC and amending those Decisions.

36 Commission communication on the framework for action in the field of public health, COM (93) 559 final, 24 November 1993; Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the state of health in the European Community, COM(95)357 final, 19.07.1995.

37 The list includes cancer, cardio-vascular diseases, communicable diseases, mental illness, musculo-skeletal conditions, and respiratory diseases.

include defective or poorly designed products.[38] All this does not give a constitutional mandate to legislate on product safety issues on grounds of public health, as the Court of Justice held in the Tobacco Advertising decision referred to above.[39]

It has been seen above that Article 95 does not refer to the protection of public health, which is provided for by Article 152. Also, Article 153.3 applies the goal of protection of the health, safety and economic interests of consumers (under the heading "consumer protection") to measures adopted under Article 95. However, these demarcations may be becoming blurred, since the first recital to the latest amendment to the Cosmetics Directive, which is adopted under Article 95 and without reference to Article 153, states that that Directive's "main objective [is] the protection of public health". This may be an error, but it is a significant revelation of the real justification and purpose of product safety legislation.

Health aspects in decisions on Community trade

A further reference to health issues in the EC Treaty is Article 30, which may shed some light on Community policy on health issues, not least because a greater amount of case law has emerged under Article 30 than under Article 95. Article 30 (formerly 36), as is well known, provides exemptions to the prohibition under Articles 28 and 29 of quantitative restrictions on imports and exports. Such discriminatory barriers to trade would be justified under the exemption on grounds, inter alia, of the protection of health and life of humans, animals or plants. It is not relevant to analyse here the extensive case law on Article 30, but some points emerge from the cases that are relevant to the current enquiry on the Community's approach to product safety.

The Court of Justice has established fairly clear principles in interpreting Article 30,[40] which reveal a significant point of relevance for this enquiry, which is the extent to which Member States retain significant power and discretion over national policy on public health issues, and by implication product safety issues.

The first principle established by the Court of Justice is that Member States' claims seeking to invoke the protection of life and health exemption will be subject to close scrutiny in order to determine whether that is the real purpose behind the trade restriction.[41] Secondly, in the absence of Community harmonisation measures, and where there are uncertainties over the scientific

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38 The list is: drunken driving, unsafe behaviour, defective or poorly designed products and services, environmental problems.

39 Case C-376/98, above.

40 See for example P Craig and G de Burca, *EU Law: Text, Cases, and Materials*, (Oxford, 2ed, 1998).

41 See Case C-40/82, *Commission v United Kingdom*, [1982] ECR 2793.

assessment of the safety issues, the Court of Justice will first decide whether the public health claim is sustainable in principle, and then leave the member states to decide on the appropriate degree of protection to assure their citizens, but subject to application of the principle of proportionality, under which the member states' power of prohibition is restricted to what is necessary to attain the legitimate aim of protecting public health.[42] Thirdly, where harmonisation measures exist, the Article 30 exemption will generally not be available: where the measures afford total harmonisation, the exemption is not available at all, although where the measures are more limited then national regulations can be lawful provided they are proportionate and do not constitute a means of arbitrary discrimination.[43]

Thus, in the second type of case, the Court of Justice has held that, in relying on Article 30,

> "it is for the member states, within the limits imposed by the Treaty, to decide what degree of protection they intend to assure and in particular how strict the checks to be carried out are to be. Nevertheless it emerges from Article [30] that national rules or practices which do restrict imports of pharmaceutical products or are capable of doing so are only compatible with the Treaty to the extent to which they are necessary for the effective protection of health and life of humans. National rules or practices do not fall within the exemption specified in Article [30] if the health and life of humans can be as effectively protected by measures which do not restrict intra-Community trade so much. In particular Article [30] cannot be relied on to justify rules which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure unless, in the absence of the said rules or practices, this burden or expenditure clearly would exceed the limits of what can reasonably be required."[44]

In the second situation identified above, the Court has held that although a Member State may require a product that has already received approval in another member state to undergo a fresh procedure of examination and approval, the former state is not entitled unnecessarily to require technical or chemical analyses or laboratory tests, or be subject to unnecessary control expenses, when the same analyses and tests have already been carried out and their results are available to the authorities or may at their request be placed at their disposal.[45] The Court's approach is therefore to expect collaboration between Member State authorities so as to avoid unnecessary expense and duplication.

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42 Case 174/82, *Officier van Justitie v Sandoz BV* [1983] ECR 2445; Case 124/81, *Commission v United Kingdom* [1983] ECR 203; Case C-473/98 *Kemikalieinspektionen v Toolex Alpha* [2000] ECR I-5681 in which national legislation laying down a general prohibition on the use of trichloroethylene for industrial purposes but establishing a system of individual exemptions granted subject to conditions was upheld; Case C-217/99, *Commission v Belgium* [2000] ECR I-10251; Case C-55/99, *Commission v France* [2000] ECR I-11499.

43 Case 4/75, *Rewe-Zentralfinanz GmbH v Lanwirtschaftskammer* [1975] ECR 843; Case C-317/92, *Commission v Germany* [1994] ECR I-2039; Case 17/93, *Openbaar Ministerie v Van der Veldt* [1994] ECR I-3537; Case C-320/93, *Lucien Ortscheit GmbH v Eurim-Pharm Arzneimittel GmbH*, [1995] 2 CMLR 242.

44 Case 104/75, *Officier van Justitie v Adrian De Peijper*, [1976] ECR 613, paras 15 - 18.

45 Case 272/80, *Frans-Nederlandse Maatschappij voor Biologische Producten BV* [1981] ECR 3277; Case C-400/96, *Harpegnies* [1998] ECR I-5121.

In the third situation identified above where harmonisation measures exist but are incomplete, the prohibition of importation of medicinal products that are legally marketed and subject to a marketing authorisation in a member state of export and subject to a manufacturing authorisation in the importing member state, simply because the products in question are not provided with packaging and a package leaflet complying with statutory requirements in the importing state, is not necessary for the effective protection of human life and health.[46] However, at a stage of incomplete harmonisation and in the absence of a procedure for Community authorisation or mutual recognition of national authorisations (in the particular case, for medicinal products), Member States are entitled to prohibit entirely the marketing in their territory of products that have not been authorised by the competent authorities.[47] If it is demonstrated that there is in fact a risk to public health arising from the coexistence of new and old (a parallel import) versions of the same medicinal product on the market, such a risk may justify restrictions on the importation of the old version in consequence of the withdrawal of the marketing authorisation of reference by the holder thereof in relation to that national market: the question of the existence and reality of the risk to public health is primarily for the competent authorities to determine.[48]

In a further example, the Court held that, where a particular Directive does not exhaustively harmonise safety limits, a national policy of zero tolerance on a safety issue (the presence of Listeria monocytogenes in fish products) that could be covered under such a Directive but is not, can be justified on the ground of protection of the health of humans and animals, as an exception to Article 30.[49]

In cases involving incomplete harmonisation and Article 30, the Court has been active in expressing views on different measures which it considers to be equally effective in protecting health and life but are more or less restrictive of intra-Community trade. Thus, it has held a simple ban by a Member State on the importation of freshwater crayfish that were in circulation in other Member States to be in breach of Article 30 since it considered that other more limited measures, such as health checks or sample checks where consignments were accompanied by a health certificate, would have been adequate.[50] Similarly, a Member State cannot justify the imposition of inspection

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46 Case C-347/89, *Freistaat Bayern v Eurim-Pharm GmbH*, [1991] ECR I-1747.

47 Case C-320/93, supra: there would seem no reason why similar reasoning should not apply by analogy for products subject to requirements other than the marketing authorisation requirements that apply for medicinal products.

48 Case C-172/00, *Ferring Arzneimittel GmbH v Eurim-Pharm Arzneimittel GmbH* [2002] ECR I-6891

49 Case C-121/00, *Criminal proceedings against Hahn*, [2002] ECR I-9193.

50 Case C-131/93, *Commission of the European Communities v Federal Republic of Germany*, [1994] ECR I-3303.

and certification requirements on butter that is already pasteurised, and in the absence of evidence of health problems in other states.[51]

The above case law reveals the extent to which Member States retain considerable autonomous discretion over their domestic health policies in the absence of total Community harmonisation provisions, which can extend to a zero tolerance policy on a safety issue, thereby justifying banning the importation or sale of a specific product type, even though it is permitted in other Member States.

Conclusions

There are several key findings from the above analysis. The constitutional basis of the regulatory legislation considered here rests on trade and economic considerations. The substantive purpose of the legislation, namely the achievement of safety, is not given legal status, other than through an instruction to the Commission that the legislation will take as a base a high level of protection of health and safety, and the Council and Parliament will seek also to achieve this objective. Such statements are little more than political aspiration. What is meant by a "high level" is unclear. Further, individual Member States retain significant competence to determine their own policies on the level of protection that they consider domestically appropriate.

The Treaty does not provide a rationale as to why certain product sectors were deemed worthy of regulation at all or in priority to others. Certainly, neither of the Treaty provisions relating to consumer protection or public health form a jurisdictional base for legislating in relation to product safety, although both refer, as does Article 95, to the general aim of ensuring a high level of protection.

Indeed, there are no provisions in the Treaty that would found product safety regulatory legislation other than Article 95. It is curious that although consumer protection, the protection of public health and the maintenance of a high level of safety of the population are important issues for European legislators and citizens, and worthy of mention in the Treaty, there is no direct jurisdictional power to institute measures to achieve any of these three goals. Whilst this has not been a major impediment to date, in that only one measure (the Tobacco Advertising Directive) amongst a large corpus of legislation that has been passed by the Community legislator was held not to have jurisdictional competence, there may have been other measures (such as controls on

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51 Case C-205/89, *Re Butter Imports: E C Commission v Greece* [1991] ECR I-1361.

distribution of unsafe products) that might have emerged if there had been a wider jurisdiction, and there may well be such measures that might recommend themselves in future.

The key issue is whether current law can maintain public safety in relation to the use of products, particularly at a high level of protection, if it does not have competence to introduce measures based specifically on safety criteria, rather than market-building criteria. If not, this raises the issue of whether the Treaty should be revised so as to provide proper jurisdiction. The current position is certainly illogical. But whether a change is justified as a pre-emptive step should be measured in the light of assessment of data on the success of the mechanisms that currently exist for achieving product safety, which are points discussed further below.

4. MEDICINAL PRODUCTS

Overview of the regulatory provisions for medicinal products

The Community's regulatory system for medicinal products is the oldest, most extensive and most complex of any vertical product regulatory system, comprising "a very substantial body of Community legislation and case law".[52] It has been amended regularly since the first Directive was introduced in 1965 as a response to the Thalidomide tragedy,[53] at which time some countries already had regulatory systems in place,[54] and the system is still evolving.[55]

Authorisation of marketing

The regulatory system for medicinal products comprises the following principal points.[56] The person responsible for marketing a medicinal product within the Community must apply to a competent authority for, and be granted, a marketing authorisation for the product.[57] The application must be accompanied by, first, specified particulars and documents, which record the data generated from prescribed tests and trials on the product,[58] and, secondly, the written opinion of experts in analysis, pharmacology and clinical medicine, who attest that the relevant tests have been carried out and that the results and the product offer the acceptable levels in relation to, respectively, manufacturing controls, toxicity and clinical safety.[59]

According to the policy set out in legislative recitals, regulatory decisions in relation to the grant of marketing authorisations are to be based on three criteria, namely safety, efficacy[60] and quality, which

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52 Francis G Jacobs, Advocate General, "Foreword", in R Goldberg and J Lonbay (eds), *Pharmaceutical Medicine, Biotechnology, and European Law*, (Cambridge, 2000).

53 H Teff and C R Munro, *Thalidomide: the legal aftermath*, (Saxon House, 1976); J P Griffin and R R Shah, "The development of the control of human medicines in Europe from classical times to the year 2000" in J P Griffin and J O'Grady, *The Textbook of Pharmaceutical Medicine*, (BMJ Books, 4 ed, 2002); J Abraham and G Lewis, *Regulating Medicines in Europe*, (Routledge, 2000), ch 3.

54 For example the United States of America introduced the Federal Food, Drug, and Cosmetic Act in 1938 and Sweden introduced controls in 1934: see J Abraham and G Lewis, *op cit.*

55 In addition to the introduction of further technical requirements, an example of extended coverage based on safety issues relates to homeopathic and herbal medicinal products: see respectively Directives 92/73/EEC and 2003/63/EC.

56 A fuller exposition is C Hodges, "The Regulation of Medicinal Products and Medical Devices" in I Kennedy and A Grubb (eds), *The Principles of Medical Law*, (Oxford, 2ed, in press 2004).

57 Regulation (EEC) 2309/93, Article 3; Directive 2001/83/EC, Article 6.1.

58 The very extensive list of particulars and documents is prescribed at Directive 2001/83/EC, Article 8.3 and Annex I, which includes the requirement for the results of physico-chemical, biological or microbiological tests, toxicological and pharmacological tests, and clinical trials.

59 Directive 2001/83/EC, Article 12; Regulation (EEC) No 2309/93, Article 6.

60 The concept of the protection of public health means that a medicinal product must not only not be harmful but also must be effective, catching products which are not sufficiently effective or which do not have the effect which their presentation might lead to expect: Case C-219/91 *Ter Voort* [1992] ECR I-5485; Order of the President of the Court in Case C-471/00 *Commission of the European Communities and Cambridge Healthcare Supplies Ltd* 11 April 2001; Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan GmbH and Others v European Commission* 26 November 2002.

are designed to ensure the protection of public health[61]:

> "Whereas in the interest of public health it is necessary that decisions on the authorisation of ... medicinal products should be exclusively based on the objective criteria of the quality, safety and efficacy of the medicinal product concerned to the exclusivity of economic or other considerations; whereas these criteria have been extensively harmonised by Council Directive [2001/83/EEC][62]...; whereas, however, Member States should exceptionally be able to prohibit the use on their territory of medicinal products which infringe objectively defined concepts of public order or public morality ..."

However, reliance on a criterion of safety gives rise to difficulties, as was recognised by Mustill LJ in considering whether a product can be safely administered:

> ".. there is no absolute standard of safety. Very few drugs are entirely free from the risk of inducing adverse side effects in some patients. The question must always be whether the degree of risk is sufficiently low to be acceptable, and this cannot be addressed without an appreciation of the benefits to be gained from taking a risk of that degree."[63]

The President of the Court of Justice has said that in decisions on grant, variation, suspension or revocation of a marketing authorisation, the requirements of public health unquestionably take precedence over economic considerations, and involve a benefit/risk assessment, in which the degree of harmfulness which the authority may regard as acceptable depends on the benefits which the medicinal product is considered to provide.[64]

As specified in subsequent recitals, other key features of the system comprise: the importance of making decisions of the highest possible quality; that regulatory decisions that are of sufficient importance in relation to safety issues should be taken by a single authority on the basis of the best available, independent scientific evaluation and advice; that pre-marketing evaluation of medicinal products is insufficient to guarantee their safety and must be supplemented by the post-marketing mechanism of the pharmacovigilance system;[65] and that safety considerations require that regulatory

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61 Regulation (EEC) No 2309/93, recital 3 (see also recitals 7 and 8); virtually identical wording had been used in Council Directive 93/93/EEC, third recital, which amended the primary measure, Council Directive 65/65/EEC, but curiously this wording was omitted from the consolidating measure, Directive 2001/83/EC, although it was apparent from the complete text that no change in policy was intended. The three criteria are set out in the Medicines Act 1968, section 19, but the Community provisions are applied to nearly all products by virtue of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994 No 3144.

62 In Council Regulation (EEC) No 2309/93 this wording is in the subsequent recital.

63 *Organon Laboratories Limited v Department of Health and Social Security* [1990] 2 CMLR 49 CA, at 78.

64 Order of the President of the Court in Case C-471/00 *Commission of the European Communities and Cambridge Healthcare Supplies Ltd* [2001] ECR I-02865. Directive 2001/83/EC, Recital 7 states that "the concepts of harmfulness and therapeutic efficacy can only be examined in relation to each other and have only a relative significance depending on the use for which the medicinal product is intended. The particulars and documents which must accompany an application for a medicinal product demonstrate that potential risks are outweighed by the therapeutic efficacy of the product."

65 See Regulation (EEC) No 2309/93, Article 21 and following and Directive 2001/83/EC, Article 103 and following. See Appendix 1.

controls exist for the provision of product information and the monitoring of good practice standards. Such standards cover virtually every aspect of the testing,[66] manufacture and marketing of medicinal products.

The dual approval systems

Two regulatory systems for medicinal products are in fact operated in the Community. Under the centralised system, marketing authorisations are granted by the Commission, after advice from the European Agency for the Evaluation of Medicinal Products ("EMEA") on the basis of expert assessment and advice given by the Committee for Proprietary Medicinal Products ("CPMP"), that are valid throughout the Community.[67] Under the mutual recognition system, authorisations granted by national authorities are valid only within the territory of each Member State, but there is a procedure under which applications may be made for authorisations in other Member States based on an approval in one of them (the reference state).[68]

No other product sector has such a duplication of centralised and national regulatory systems,[69] and the wisdom of such continued duplication may be questioned, both on the basis that the requirement for national authorisations offends against the concept of a single market and, as will be noted below, in relation to inefficiencies and anomalies in the delivery of safety.

Controls on information, advertising, manufacture, distribution and post-marketing evaluation

The protection of public health, rather than trade policy, is specified as justifying regulation of labelling,[70] product information leaflets,[71] and advertising:[72]

> "The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.

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66 Controls include those concerning animal experiments (Directives 86/609/EEC and 87/18/EEC plus the standard on good laboratory practice) and clinical trials (Directive 2001/20/EC and the standard on good clinical practice).

67 Regulation (EEC) No 2309/93.

68 Directive 2001/83/EC, Article 28.

69 This state of affairs developed historically: when regulation was first introduced, Directive 65/65/EEC crystallised the introduction of national authorisation systems, which was arguably all that could be contemplated either in practice or politically at that stage, and reforms to the mutual recognition procedures have slowly but gradually been introduced since then, for example under Directive 87/22/EEC, which required that applications for high technology products had to be referred to the CPMP for an opinion before a (national) marketing authorisation could be granted. The centralised system introduced by Regulation (EEC) No 2309/93 was effectively established on a trial basis, in that it was restricted to certain categories of products, which are subject of extension, as noted below. The logical outcome is that the mutual recognition system will be deconstructed.

70 Directive 2001/83/EC, Article 54 and following, based on a Summary of Product Characteristics (SmPC) approved by the competent authority at the time of grant of the marketing authorisation and subject to continuous updating: ibid, Article 83.

71 Directive 2001/83/EC, Article 58.

72 Directive 2001/83/EC, Article 86 and following.

> Advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined."[73]

Authorisations granted by the competent authorities are also required for the manufacture[74] and wholesale distribution[75] of medicinal products: national provisions generally govern retail sale or supply.

What level of safety does the regulatory system deliver?

A general impression of whether the regulatory system is a success was given in a major study of the Community's pharmaceutical legislation completed in 2000. The general conclusion was:

> "There is no real perception that either the centralised or decentralised system has failed to provide a high degree of safety for patients or animals in relation to the medicinal products made available to them ...."[76]

Interestingly, statistics on safety were not quoted in that study, and that omission seems to indicate of a lack of concern over the prevailing level of safety. If a systematic approach were to be taken, one would expect data to be collected which would permit comparison between the number of products used and authorised, and the number withdrawn, and the incidence of adverse reactions reported. Such an approach seems not to be taken, at least publicly. Some data can be assembled from various sources, as set out in Appendix 3.

The pharmaceutical industry considers that adverse events are "very rare"[77] and that it would not be possible to detect any unsafe aspect of a marketed pharmaceutical product any earlier than is currently the case given the regulatory and pharmacovigilance system.[78] It notes a very low level of

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73 Directive 2001/83/EEC, Recitals 40 and 45.

74 Directive 2001/83/EC, Article 40 and the standard of good manufacturing practice. The justification set out in Directive 2001/83/EC, Recitals 26 and 27 relates more to trade and economic issues than to safety issues.

75 Directive 2001/83/EEC, Article 77 and the standard of good distribution practice: Recital 35 states: "It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products."

76 CMS Cameron McKenna and Andersen Consulting, *Final report: Evaluation of the Operation of Community Procedures for the Authorisation of Medicinal Products*, European Commission, 2000.

77 *Position paper: Response to Product Liability Green Paper by European Federation of Pharmaceutical Industries and Associations (EFPIA)*, 1999, Conclusion.

78 Ibid, para 6.4.

compensation claims in the EU and summarises the position thus[79]:

> "The regulatory framework satisfies the EU Treaty policy of affording a high level of health and safety and the legislation itself requires standards to be updated if the state of scientific and technical knowledge changes.
>
> Evaluation of the safety of medicines by manufacturers and European regulatory authorities is a state-of-the-art function in product regulation. Summaries of product characteristics (including information on safe use, contraindications and warnings) are kept up-to-date and accurate. The pharmacovigilance system involves a collaboration between patients, physicians, manufacturers and regulators and works as an effective mechanism in swiftly identifying post-marketing adverse reactions so that appropriate action can be taken, such as revising labelling information or ultimately withdrawing a product from the market."[80]

Conclusions on the system of regulation of medicinal products

The meaning of "safety" in relation to medicinal products

A number of significant points of criticism can be made in relation to the legal tests for marketing and withdrawal of medicinal products.[81] These can be summarised as follows. First, the tests (and statements in the recitals) for both grant of an application for a marketing authorisation and for its withdrawal are different as between the centralised and mutual recognition procedures.[82] Secondly, the single test that is in fact applied by regulators is a risk-benefit test, in which benefits must be considered marginally to exceed risks.[83] Thirdly, the assessment of safety at the pre-marketing stage is provisional, in that although it is based on extensive data that has been very costly and time-consuming to produce, the knowledge of how the product reacts in use is only based on usually brief trials in quite restricted numbers of humans. An integral part of the system, therefore, is the post-marketing pharmacovigilance system, which provides, in theory, continuous data on the

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79 Ibid, para 7.2: multi-party claims were seen from 1985-2000 in the United Kingdom but 93% of these were unsuccessful: see C Hodges, *Multi-Party Actions*, (Oxford, 2001).

80 Ibid. Paras 4.2 and 4.3.

81 See chs 8 and 12.

82 Respectively, that the application shall be refused if it appears that the safety of the product has not been adequately or sufficiently demonstrated, or that it proves that the product is harmful. The "proves to be harmful" test seems more appropriate to the post-marketing situation and is, indeed, specified for this under the mutual recognition system: it is not entirely clear whether that test or any test is applied in relation to centrally-authorised products.

83 As discussed at ch 8, the only relevant references to a risk-benefit test are in recitals; in the centralised system Regulation (EEC) No 2309/93, recital 15 justifies the authorities' powers of rapid withdrawal of a product from the market where it "presents an unacceptable level of risk under normal conditions of use", and in the mutual recognition system Directive 2001/83/EC, recital 15 states that "the particulars and documents that must accompany an application for a marketing authorisation demonstrate that potential risks are outweighed by the therapeutic efficacy of the product" [the wording is curious and arguably does not impose an obligation but is a mere statement of general aspiration]. The EMEA's Guidelines on pharmacovigilance (Notice to marketing Authorisation Holders, European Medicines Evaluation Agency, para 1.6: see further discussion at chapter 11 and Appendix 2.) refer to the situation where a product has "a satisfactory balance of benefits and risks under the conditions defined in the [Summary of Product Characteristics], on the basis of the information available at that time."

product's use, notably through adverse reaction reports but also through specific "Phase IV" studies. Protecting public health through use of medicines is, therefore, and must be *a continuous dynamic process of reassessment* that lasts for at least the commercial lifetime of each product.

It follows that there is a strong case for rationalising the legal tests into a single test, which is both consistent and transparent. There is currently no clarity over the criteria that are adopted in marketing or post-marketing safety decisions. Further, the system is heavily dependent on decisions made by medical and scientific experts. The validity and consistency of decisions is not transparent, and this may lead to issues of public confidence in the system. Since it is clear that there is no such thing as absolute safety, particularly in relation to drug safety, all decisions on the authorisation of medicinal products necessarily involve subjectivity in evaluation. However, if the system necessarily has to involve decisions that are, to a great extent, taken by experts, transparency and public confidence would be increased if there were a public statement of criteria of what level of adverse reactions are or are not acceptable for specific products or product types, and a publicly available comprehensive matrix of decisions that have been taken so that a comparative judgment could be made of the mutual coherence or acceptability of individual or multiple decisions.

Although a risk-benefit test itself raises similar issues, its adoption would at least realistically recognise that different products have different risks and benefits, and that individual patients and society will tolerate higher risks in circumstances where their medical conditions are more serious and there is greater potential for benefit.[84]

Given that regulators' approach to decision-making involves a subjective element, weight might be given in some decisions to whether the regulator anticipates that a product would lead to adverse reactions of a type or incidence such as to generate significant public concern in the regulatory system. This would be a long way from the approach that is seemingly adopted in the legislation, which gives the impression of quantitative decisions based on submission of scientifically verified data. There may certainly be some products, such as those involving reproduction or the brain, or types of reactions, such as carcinoma, which give rise to greater concern than others. Given the absence of clarity in the legal framework over both the definition of the test for (initial and continued) approval of marketing, and over the criteria that are to be applied in reaching and evaluating individual risk/benefit decisions, coupled with the fact that decisions involving medicinal

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[84] AIDS and vCJD patients have been prepared to accept untested drugs whose efficacy and risk profile are unknown. In this context, it is relevant that there are no known cures for half of the world's diseases, and that Community policy is to introduce a procedure allowing a conditional authorisation that will allow products of major public health interest to be given conditional access to the market whilst certain studies are finalised: Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions: Life sciences and biotechnology – A Strategy for Europe, COM(2002) 27, OJ C 55/3, 2.3.2002.

products are often difficult and complex, it is intriguing that there is an absence of public complaints from industry questioning licensing decisions made by regulators.[85] The relative absence of public disputes over this point could be a significant indication either that the system is working tolerably well, or that it has utterly broken down.

Another indicator of the reliability of the system is the extent to which there are differences of view between different regulatory authorities. Some such differences are to be anticipated given the scope for differing views on issues that involve judgment. In 2001-02, there was agreement between the assessments of the Medicines Control Agency and other EU regulators in 97.5% of cases, and between the MCA and its expert committee, the Committee on Safety of Medicines, in 96% of cases.[86] It is difficult to judge whether these data indicate a high level of agreement or a significant level of disagreement.

The regulatory mechanisms

The extensive and complex provisions that apply in the pre- and post-marketing phases of medicinal products give rise to various difficulties. Commentators from within industry note the lack of predictive precision of animal tests,[87] and conclude in relation to the system as a whole:

> " It seems obvious that premarketing clinical trials, which seldom study more than 1000-2000 patients, are incapable of evaluating safety for any but the most common adverse reactions, and that spontaneous reporting, which is so inefficient that a 10-15% reporting rate would be considered quite exceptional, is not an appropriate method for new drugs."[88]

Noting that the evaluation of safety for medicinal products involves five basically different techniques (clinical trials, spontaneous reporting, computerised databases, prescription event monitoring, and ad hoc methods) the same commentators have concluded that

> "A continuing problem is the lack of attention that has been paid to the capabilities of each method.... Each of the methods has serious defects; numbers of patients and costs are negative factors for cohort studies; completeness of data and validation are problems for

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85 A rare instance of litigation on a safety issue involved Halcion, which resulted in different views being taken by the authorities in, on the one hand, the United Kingdom, followed by others including Finland and Norway, and, on the other hand, the Community (CPMP): see J Abrahams and G Lewis, *Regulating Medicines in Europe*, (Routledge, 2000), p 147. In contrast, there has been a number of instances of litigation over commercial aspects of regulation: see for example I Dodds-Smith "Data protection and abridged applications for marketing authorisation in the pharmaceutical industry", in R Goldberg and J Lonbay (eds), *Pharmaceutical Medicine, Biotechnology, and European Law*, (Cambridge, 2000).

86 National Audit Office, *Safety, quality, efficacy: regulating medicines in the UK*, (The Stationery Office, 2003).

87 A P Fletcher, "Drug safety tests and subsequent clinical experience", *J Roy Soc Med* 1978; **71**:693-6.

88 A P Fletcher and S Shaw ,"The safety of medicines", in J P Griffin and J O'Grady, *The Textbook of Pharmaceutical Medicine*, BMJ Books, 4ed, 2002.

computerised studies; and lack of a clear hypothesis or poorly defined diagnostic criteria are incompatible with high-quality case-control studies..."[89]

It is interesting that the normal tests and data requirements were retained when a simplified system was introduced in 2000 for "orphan" products (such as those which are intended to treat life-threatening or chronically debilitating conditions affecting not more than five in ten thousand persons in the Community, yet without incentives are unlikely to be commercially marketed):[90] the policy statement was made that patients with the relevant conditions deserve the same quality, safety and efficacy.[91] Commercial incentives were adopted[92] rather than diluting the safety requirements, although the EMEA will give assistance to applicants on means of satisfying the requirements.

Criticisms: bias and secrecy

The pharmaceutical regulatory system is not without its critics, including consumer representatives[93] and some academics.[94] The principal complaints that are relevant for present purposes are those of potential systemic bias and secrecy.[95] It is undoubtedly true that the system provides a complexity of competing interests which a properly regulated society must seek to balance. Hancher has aptly used the term "multi-regulation"[96] to describe the overlapping interests of producers (whose aim is to maximise profit, but will only achieve this where they retain their reputation for selling safe products[97]), the public (who rely on both the safety of products and the profits of industry), and regulators/government (whose roles are to ensure safety and promote public health; to promote industrial profitability, innovation and economic health for citizens, through ensuring sponsorship

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89 A P Fletcher and S Shaw, *op cit.*

90 Regulation (EC) No 141/2000 and Commission Regulation (EC) No 847/2000. The Community's general approach copies that of a number of other countries, based on the United States' Orphan Drug Act of 1983.

91 Regulation (EC) No 141/2000, recital 7.

92 Such as 10 year marketing exclusivity period, access to the centralised procedure fee exemptions and research funding.

93 A Chetley, *A Healthy Business? World Health and the Pharmaceutical Industry*, (Zed Books, 1990); Anon, *Pharmaceuticals: A Consumer Prescription: A discussion paper on the structure and regulation of the pharmaceuticals industry*, (National Consumer Council, 1991); Anon, *Balancing acts: conflicts of interest in the regulation of medicine*, (National Consumer Council, 1993); C Medawar, *Power and Dependence: Social Audit on the Safety of Medicines*, (Social Audit, 1992); T J Moore, *Deadly Medicine: Why Tens of Thousands of Heart Patients Died in America's Worst Drug Disaster*, (Simon and Schuster, 1995); B Mintzes and C Hodgkin, "The consumer movement: from single-issue campaigns to long-term reform" in P Davis (ed), *Contested Ground: Public Purpose and Private Interest in the Regulation of Prescription Drugs*, (Oxford, 1996).

94 L Hancher, *Regulating for Competition*, (Oxford, 1990); J Abraham, *Science, Politics and the Pharmaceutical Industry: Controversy and bias in drug regulation*, (UCL Press, 1995). K Abbasi and R Smith, 'No more free lunches', *BMJ* 2003; 326; 1155-6 and articles cited.

95 For discussion of whether unfavourable studies may not be published or reported quickly enough see 'SSRIs: suicide risk and withdrawal', *Lancet*, 361, June 14, 2003, 1999 and J Laurance, 'Seroxat ban raises doubts over drug licensing system', *The Independent*, 11 June 2003.

96 L Hancher, "Pharmaceutical Policy and Regulation: Setting the Pace in the European Community" in P Davis, *op cit*, p 180.

97 As discussed at ch 19, the protection of reputation is important for larger companies with well known brands and/or significant sales: unlike some other product sectors, the pharmaceutical sector does contain a significant segment of such companies.

but also competition; and, in some states, to purchase and pay for drugs consumed, leading to concern to restrict expenditure).[98]

Safety as shared goal for responsible companies and regulators

The fact that all of these operators share the safety goal has not always been recognised.[99] Although that the legal origin of all the Community's product regulation lies with trade issues and the goals of achieving a high level of protection of consumers and of public health are more recent additions, any assertion that the system is biased towards the interests of industry and trade over the interests of patients and public health[100] does not withstand empirical testing against what should be the appropriate criterion, namely the achievement of safety. Abraham and Lewis concluded from a study of the behaviour of regulators, industry and consumers in three national medicines regulatory systems that

> "Modern national drug regulation is not a proxy for medical accidents and the misfortunes of drug disasters but, above all, a product of the state's negotiation with, and accommodation of, organised industrial interests."[101]

In support of this, the authors cite what they identify as the response of regulatory authorities in all three countries studied to pressure from industry to reduce regulatory review times and to increased dialogue with industry,[102] but the above conclusion is questionable since they do not in fact examine data on safety.[103] Whilst one main purpose of the legislation may relate to trade matters, the actual functions of almost all of the Community institutions[104] and individuals that are involved in product

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98 The existence of potentially conflicting objectives is accepted by the UK Medicines Control Agency, which regards the situation as workable given the existing safeguards: National Audit Office, op cit.

99 Hancher commented in 1989 that safety regulation is perceived as hindering the process of innovation (L Hancher, *Regulating for Competition*, (Oxford, 1990), pp 13, 26), although by 2003 the pharmaceutical industry accepts safety regulation as normal procedure, as appears from the general tenor of works such as J P Griffin and J O'Grady (eds), *The Textbook of Pharmaceutical Medicine*, (BMJ Books, 4th ed, 2002). But the Community authorities are content with the existing balance of competing interests: Council Conclusions of 29 June 2000 on Medicinal Products and Public Health 2000/C 218/04, OJ C 218/10, 31.7.2000.

100 J Abraham and G Lewis, *op cit*, p 1.

101 J Abraham and G Lewis, *op cit*, p 79.

102 Maintaining dialogue with industry is a recognised technique of regulatory agencies and can be justified as an efficient use of resources and effective in achieving goals: see R Cranston, *Regulating Business: Law and Consumer Agencies* (Oxford, 1979) and below ch 12.

103 The data is somewhat confusing. One report is that during the 1990s, for example, the total number of drugs withdrawn from the US, market because of concerns about patient safety remained constant, in the range of one to three a year: the percentage dropped from 3.5% of newly approved drugs between 1984 and 1988 to 1.2% between 1994 to 1998: J D Kleinke, "Commentary: Much ado about a good thing" , *BMJ*, 16 November 2002, Vol 325, 1168, quoting *Parexel's Pharmaceutical Statistical Sourcebook*, (Tufts Center for the Study of Drug Development, 2001) 197. Another report is that the percentage of drugs withdrawn from the US market rose from 3.10% in the 8 year period prior to the introduction of the Prescription Drug User Fee Act in 1992 to 3.47% in the following 8 years, during which time approval times for standard drugs also dropped from a median of 27 months to 14 months: Leader, "New leadership for the FDA", *Lancet*, Vol 360, 19 October 2002, 1183.

104 The EMEA, the CPMP, the national medicines agencies are concerned with safety whereas other governmental ministries or bodies deal with trade/policy/purchasing; the Commission has a function encompassing both safety/regulatory and trade/policy issues.

regulation in fact revolve almost exclusively around safety issues. Commercial enterprises with significant public shareholding and reputation, as are many operators in the pharmaceutical sector, have incentives to defend these values through concentration on safety issues. This is not to argue that the impact of regulation should only be directed at smaller or less reputable enterprises.

Time for a new evaluation based on safety performance?

The argument here is not that improvements cannot be made to the system, or that more empirical safety data should not be produced and evaluated. Given the drawbacks with ascertaining the safety of medicines with use of any of the five techniques referred to above, each of which has developed individually during the past 38 years without there being a coherent integrated plan or assessment, a logical way forward at this stage would be to study the effectiveness and cost effectiveness of pre- and post-market mechanisms as a whole, so as to conclude whether improvements could be made in the safety of medicines and in the cost-effectiveness of the system.[105] Various points are undeniable: firstly, use of medicines will continue; secondly, their use will continue to entail safety issues; thirdly, despite the fact that the general public believes medicines to be safe, there will continue to be cases where significant adverse events occur, thereby undermining confidence in the system, the authorities and commercial operators; fourthly, the level of expenditure on pre- and post-marketing mechanisms for medicines is very substantial. In these circumstances, two main outcomes seem possible: either the public must be educated to accept that medicines cannot always be "safe", in the way in which that term is currently used in common parlance and in the legislation; or, if political adherence is to be maintained to the policy that medicinal products are "safe", increasing expenditure may be necessary on extensions to the pre- and post-marketing requirements.

Areas for improvement

The development of medicines regulation is a feature of all first-world states, involving harmonisation at an international level, and the EU has taken the lead in this process in the harmonisation of regulatory standards for pharmaceuticals across the world.[106] There are many plus points in the Community's approach: extensive, clear and evolving technical requirements, so that there can be little absence of certainty as to the tests and procedures that are required; a generally high quality of data on which decisions are based;[107] a high level of scientific and technical review of

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105 A P Fletcher and S Shaw, *op cit*, suggest that the way forward would be "to limit the massive burden of premarketing testing of new drugs, which threatens the continuation of research in the pharmaceutical industry, and to establish methods of investigation in the postmarketing phase that would provide the necessary seafeguards".

106 J Abraham and G Lewis, *Regulatory Medicines in Europe: Competition, expertise and public health* (Routledge, 2000).

107 Significantly, the introduction of standard of good clinical research practice from the late 1980s was followed by initiatives from industry in the early 1990s on mechanisms to take professional sanctions against physician

pre-marketing data; an increasingly sophisticated pharmacovigilance system that facilitates rapid electronic communication of adverse event data and swift, expert assessment; increasing centralisation, so as to deliver speed and consistency of decisions and review of data, as well as high quality. The system also delivers high manufacturing quality of products.[108]

Various comments can be made from the safety perspective on the detailed amendments that are being made to the system as a result of the 2000/2001 review. Strengthening of pharmacovigilance by more regular reporting and ensuring consistency across the EU are plus points, as are the strengthening of the EMEA scientific committees. The moves towards further central approvals may have no effect on safety, given the existing high quality of national evaluations, but can be supported in principle on the basis of being part of an overall trend towards consistent decisions based on the best scientific evaluation.[109] The shortening of time limits and granting of conditional or abbreviated approvals raise safety concerns but these may be theoretical if the quality of evaluation of applications remains high and if pharmacovigilance on conditionally approved products remains focused.

As discussed in chapter 12, centralised co-operation on pharmacovigilance and use of electronic systems of communication and of access to patient and regulatory databases is certainly essential, in view of the need to maximise the statistical power of the system and to provide generation of signals at the earliest opportunity. In this regard, more could be done within some individual member states to provide access to patient records held by GPs, hospitals and clinics and for reporting/recording to be compulsory.

Hancher, writing in 1989 before a series of reforms were introduced towards centralisation and strengthening of the system during the 1990s, rightly commented that the implementation of legislation on product safety has to be seen as a dynamic process, and that the regulatory bodies would increase in experience, expertise and hence power, as systems evolved and as scientific knowledge of pharmaceutical processes improves.[110] This seems to be happening. The EMEA and

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investigators who produced fraudulent data: see S Lock and F Wells (eds), *Fraud and Misconduct in Clinical Research*, (BMJ Publishing Group, 2nd ed, 1996).

108 Failures of GMP are rare in this industry. For one example see the recall of hundreds of thousands of doses of polio vaccine because of theoretical risk of BSE contamination: D Pilling, "Vaccine recalled amid BSE concern", *Financial Times*, 21 October 2000. However, there is scope for both research and marketing fraud, given the potentially significant financial rewards: see I Karacs, "Phoney cancer drug exposes EU shambles", *Independent on Sunday*, 26 August 2001.

109 Officials in some member states, especially those that currently have strong national agencies, fear that the extension of the centralised system will lead to loss of their expert staff and a diminution of their effectiveness: see National Audit Office, op cit, para 1.24. This need not be the case if there is a suitable balance maintained between expertise required at central and national levels, which does not seem to be an insuperable problem.

110 L Hancher, *op cit*, p 109; a point subsequently echoed by J Abraham and G Lewis, *op cit*, p 11.

its expert committees have established a sound scientific reputation[111] and the pooling of the regulatory power of the member state authorities that its creation represented[112] has given it significant strength. This is true despite the fact that it has such a small permanent staff that its reliance on national experts and officials makes it a "virtual" agency. Issues of transparency have been addressed by website publication of the European Public Assessment Report (EPAR) for every product authorised under the centralised procedure as soon as an approval decision is taken.[113] Similar information should be produced for medicinal products approved nationally.

Many commentators are familiar simply with a particular regulatory system, and it is important to note on a comparative basis that several significant features of the system for medicinal products are unique and of particular value in assisting safety. In particular, there are the sheer extent of pre-marketing testing requirements, the comparative sophistication of the pharmacovigilance system, and above all the continuing independent scrutiny by regulatory and scientific experts, and elements of peer review. Other vertical product regulatory systems do not have such sophistication nor such complexity as that for medicinal products.

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111 At the time that the EMEA was created, there was some concern by some Member State regulators, not shared by all or by industry, that the restriction on member states' right to object to applications, that was permitted under the previous "concertation" procedure but restricted under the mutual recognition procedure only to instances of serious public health or policy issues, would lead to a deterioration in the quality of safety decisions: see J Abrahams and G Lewis, *op cit.* Evidence has not been forthcoming that this has occurred: it would require extensive qualitative scrutiny of regulatory decisions over perhaps ten years to establish the point. One reason for deconstruction of the concertation procedure was to remove the ability of individual member states to object to products which would have harmed national industry or budgets.

112 A Cuvillier, "The role of the European Medicines Evaluation Agency in the harmonisation of pharmaceutical regulation", in R Goldberg and J Lonbay (eds), *Pharmaceutical Medicine, Biotechnology, and European Law*, (Cambridge, 2000).

113 Regulation (EEC) No 2309/93, articles 12(4) and 34(4).

5. NEW APPROACH PRODUCTS

Outline of the New Approach

The Community's New Approach system[114] and its origins are described elsewhere.[115] It covers many product types.[116] The system does not involve pre-marketing assessment of a product by a competent authority or the grant of a marketing authorisation. Instead, the onus of ensuring and declaring that a product conforms to the legal *essential requirements* is placed on the *manufacturer* himself, although in many instances this is subject to approval by an independent technical organisation (known as a *notified body*).[117]

The manufacturer must apply an appropriate *conformity assessment* procedure to his product in order to ensure that it complies with the essential requirements, after which he must certify this fact by completing a *declaration of conformity*. There is usually a choice of conformity assessment procedures open to a manufacturer,[118] depending on a risk-based *classification* of the class into which his product falls. The two main approaches to conformity assessment are based either on an approved total quality management system audited to ISO 9000 series standard, as customised for medical devices with EN 46000 series standard, or individual product assessment. The different vertical regulatory product systems can provide for different conformity assessment procedures, adapted from different approved modules.[119]

The essential requirements relate to the *safety* in use of the product, including labelling requirements, but are principally expressed in terms of scientific and technical *performance* characteristics. Efficacy, as

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114 Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards, OJ 1985 No. C 136/1, 4.6.85; Council Resolution of 21 December 1989 on a global approach to conformity assessment, OJ 1989 No. C 10/1, 16.1.90; Commission Communication on the development of European Standardisation of 16 October 1990, OJ No. C 20/1, 28.1.91, paragraph 75.

115 *Guide to the implementation of directives based on the New Approach and the Global Approach*, (European Commission, 2000), http://europa.eu.int/comm./enterprise/newapproach/newapproach.htm; G Howells, *Consumer Product Safety* (Ashgate, Dartmouth, 1998); J Pelkmans, "The New Approach to Technical Harmonization and Standardization" 25 (1987) *JCMS* 249-269.

116 The Directives and product sectors are listed at Appendix 1.

117 See further below and ch 18. Theoretical analysis has supported the use of responsive regulatory strategies, involving self-regulation, the graduated enforcement of sanctions in "enforcement pyramids", and the involvement of multiple agencies and interests in regulatory control, as a means of overcoming the limitations of traditional "command and control" approaches to regulation: I Ayres and J Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford, 1992); P Selznick, "Self-Regulation and the Theory of Institutions" in G Teubner, L Farmer, and D Murphy (eds), *Environmental Law and Ecological Responsibility: The Concept and Practice of Ecological Self-Organisation* (1994) at 401.

118 A number of modules are specified, that offer differing control of design and production phases, with varying degrees of intervention by a notified body. The most extensive option is module H, full conformity assurance.

119 Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives, OJ No. L380/13, 31.12.90; Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives, OJ No. L220/23, 30.8.93.

such, is not a criterion. In the case of medical devices, confirmation of conformity must include evaluation of clinical data for many devices, generated from either a compilation of scientific literature or the results of *clinical investigations* on the product, for which prior ethical and regulatory approval is required. Conformity of a product with the essential requirements is denoted by affixing *CE marking* to the product. CE marking acts in effect as the passport which authorizes the product to be placed on the market and to circulate freely within the Community, and must be marked on the product.

The legal obligation is that a product must comply with the relevant essential requirements, but where the manufacturer chooses to apply a national standard which adopts a European *harmonized standard* (EN series) to an aspect of his product, conformity will be *prima facie* presumed in respect of the aspects of the essential requirements covered by that standard. Other national or international standards do not have this regulatory benefit. There is a very considerable and growing number of harmonised standards, as discussed below. Compliance with the essential requirements at the time of placing the device on the market, or declaration of this fact, should mean that the device is safe but it may later transpire that this is not the case. Manufacturers therefore have some post-marketing requirements. If a marketed product is unsafe, the *competent authority* of a member state has power under a *safeguard clause* in each Directive to take regulatory action to effect the withdrawal of the product from the market in its jurisdiction: the matter is then referred to the Commission and all member states who then coordinate their actions.

Review of the New Approach

The Commission has concluded that the New Approach is "widely recognised as highly efficient and successful" but that three aspects in particular need strengthening:[120] various issues related to notified bodies (discussed below); revision of the safeguard procedure; and strengthening of enforcement measures were proposed (these are discussed in chapter **post-m.**). The Commission's review made no comments on the prevailing level of safety or the extent to which the Directives achieved the "high level of protection" goal. The emphasis was, of course, on effectiveness and efficiency in relation to market issues, rather than safety, but some aspects that relate to safety were raised in the Commission's prior consultation:[121]

- The needs of small and medium-sized enterprises for a simple and transparent legal framework.
- The fact that the appropriate balance between pre- and post-marketing controls varies from one sector to another – some products are relatively easy to trace and check once on the

120 Communication from the Commission to the Council and the European Parliament: Enhancing the Implementation of the New Approach Directives, COM(2003) 240, 7.5.2003.

121 An open questionnaire: Consultation Document Prepared by the Directorate General for Enterprise on the review of the New Approach, http://europa.eu.int/comm./enterprise/consultations/index.htm.

market or in circulation (industrial machinery), others are not (toys, electrical appliances). In some sectors, experience showed that an adjustment of the current balance may be required, which would be addressed by revision of individual Directives.[122]

- There is a need to introduce a more coherent choice of conformity assessment modules that are more compatible with the risk categories of products, particularly extending the availability of total quality assurance (module H),[123] since manufacturers sometimes had to apply different modules for different categories of risks and to involve different notified bodies.[124]

- There is a need for mechanisms to help market surveillance authorities to trace products back to their manufacturers.[125]

Criticisms of the New Approach system

The essence of the New Approach is to place responsibility for ensuring regulatory compliance on individual industrial manufacturers or economic operators who choose commercially to exploit products under their own names: authorities are not involved in the pre-marketing procedures. The focus is essentially on pre-marketing compliance with essential requirements. Nevertheless, there is increasing realisation that post-marketing techniques are also relevant: some post-marketing vigilance requirements exist for medical devices and the 2001 extension of the GPSD introduces post-marketing obligations for both manufacturers and distributors of all consumer products. All this is in strong contrast with the system for pharmaceuticals, where the basic mechanism involves, first, an important role for competent authorities, in scrutiny and pre-marketing approval, and, secondly, a role for continuous post-marketing vigilance which is equally if not more important than pre-marketing approval.

Many industrial operatives erroneously believe that the New Approach essentially involves approval by a notified body, in the same way as if the notified body were a competent authority under the medicines system or similar to the way in which the Food and Drug Administration acts under US legislation.[126] This misconception is unfortunate, as it leads to the basic error that the manufacturer does not realise that it is he, rather than a competent authority, that has ultimate and total responsibility for safety of the product. The "game" is not to get a product past the notified body, but to ensure that it is, in fact and in all respects, safe to use.

The policy of offering manufacturers a flexible choice of conformity assessment methods produces a complex overall picture, as can be seen from Table 2. Given that large manufacturers usually adopt full conformity assurance (module H) and manufacturers of simple products tend to adopt module A,

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122 Consultation Document, section 2.1; Communication, section 2.1.

123 This was included in the proposal for amendment of the machinery Directive, COM (2000) 899 final, OJ C 154E, 29.5.2001, p 164.

124 Consultation Document, supra, section 2.2.

125 Ibid, section 2.2. Other aspects of market surveillance covered in the Consultation Document are discussed at chs 11 and 12.

126 Personal communications between various individuals and the author over several years.

there is a case for simplification. However, current policy is expansionist, by extending modules H, E and D, ostensibly to deal with the sometimes limited choice of modules where a product is covered by more than one Directive.[127]

A fundamental issue is that CE marking is not understood by the public.[128] This problem may well be connected with the complexity of the technical requirements and of the conformity assessment modules. Essential requirements are written as generalised objectives,[129] and this has been criticised as vague, both intrinsically and in relation to harmonised standards.[130] Expert knowledge may be required both to satisfy essential requirements and to assess compliance, and this raises the issues of transparency and democratic accountability. Third party certification and competent authority surveillance and enforcement may be required to address these issues. Accordingly, it is appropriate to continue this analysis by considering further the roles of notified bodies and of standards in safety processes. It should also be noted that the Commission recognises that serious issues remain to be solved over market surveillance and enforcement,[131] which are considered at chapter 12 below.

NOTIFIED BODIES

The functions of notified bodies

Notified bodies exist solely under New Approach Directives. Their function is to provide independent verification[132] that particular aspects of the design, manufacture or quality system conformity[133] have been carried out by manufacturers. They are, therefore, usually commercial testing laboratories or certification bodies,[134] to which is delegated a regulatory function after certification by the competent authority in a Member State on the basis of compliance with the appropriate standards and after notification by the Member State to the Commission. A list of notified bodies must be

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127 Communication from the Commission: Enhancing the Implementation of the New Approach Directives, COM(2003) 240, 7.5.2003.

128 Communication from the Commission: Enhancing the Implementation of the New Approach Directives, COM(2003) 240, 7.5.2003, para 2.4.

129 These are target standards, not performance or specification standards, as discussed at chapter 17.

130 G Howells, *Consumer Product Safety* (Dartmouth, 1996), p 85.

131 Communication, supra, para 2.5.

132 The delineation of the functions of notified bodies has been recognised by the House of Lords, in the context of deciding whether a product falls within one or more vertical regulatory systems (and that the views of notified bodies on such borderline issues are not conclusive): "Notified bodies in each Member State have the function largely of verification and audit rather than determination as to whether a product falls within the Directive and if so into which class it falls." *Optident Limited and Another v Secretary of State for Trade and Industry and Another* [2001] UKHL 32, 28 June 2001 per Lord Slynn of Hadley at para 26. The case decided that a tooth whitening product that was placed one the market as a medical device bearing CE marking was in fact a cosmetic, and therefore banned because it contained more than the prescribed concentration of hydrogen peroxide.

133 Exactly which of these functions is performed varies from Directive to Directive, and dependant upon which conformity assessment module is being applied.

134 Although it is irrelevant whether they are commercially-owned or State-owned.

published by the Commission in the *Official Journal of the European Communities* and constantly updated.[135] Notified bodies come under the jurisdiction of, and remain answerable to, their national authorities.[136] They may formally subcontract part of their activities (as occurs where particular expertise is required) but they remain responsible for all the activities for which they are notified.[137] Serial subcontracting will not be allowed. They must be appropriately insured to cover their professional activity and are not immune from civil liability. Notification implies that a body meets the competence criteria, that it can carry out conformity assessment activities under the directives, and also that it is willing to take part in any co-ordination activities organised by the Commission.

Notified bodies are therefore intended to provide, as a service to economic operators, the facilities for conformity assessment of products in accordance with the conditions set out in the directives in a competent, transparent, neutral, independent and non-discriminating manner.[138] Where certification of a product or system is required, the choice of a notified body is left to the manufacturer or his representative from amongst the available accredited notified bodies, and a commercial contract is entered into between the two, the terms (and particularly the price) of which are subject to normal commercial competition and negotiation. Accreditation entails laboratories, certification and inspection bodies being assessed and audited at regular internals as to their technical competence against published technical criteria by an expert third party. The EN 45000 series of standards includes the technical criteria for the operation and assessment of testing laboratories as well as those to which the accreditation bodies for testing laboratories themselves should conform. They also include the criteria for certification bodies. Conformity of a notified body to the relevant standard of EN 45000 constitutes an element of presumption of conformity to the requirements of the annexes of the relevant directive(s) but is not always in itself sufficient. Demonstration of technical capability within the scope of the directives is necessary.

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135. A list of the notified bodies designated by the Member States and the EFTA countries (EEA Members) under the new approach Directives up to 15 April 1994 was published at OJ No. C 203, 23.7.94. Approximately 1000 bodies had been notified by the end of 2002: Communication from the Commission: Enhancing the Implementation of the New Approach Directives, COM(2003) 240, 7.5.2003.

136 In the United Kingdom the relevant Government department is responsible for certification, usually on the basis of advice from the National Accreditation Council for Certification Bodies (NACCB) in the case of certification bodies or the National Measurement Accreditation Service (NAMAS) operated by the National Physical Laboratory in the case of testing and accreditation bodies. The names of the 1100 test and calibration laboratories accredited under UK national procedures are published in the NAMAS Concise Directory and in the DTI QA Register.

137 The sub-contracting of work to notified bodies is subject to certain conditions guaranteeing:
- The competence of the establishment operating as a sub-contractor on the basis of conformity with series EN 45000 standards, and the capability of the Member State that has notified the sub-contracting body to ensure effective monitoring of such compliance,
- The ability of the body notified to exercise effective responsibility for the work carried out under sub-contract.

138 See fn 4 above. The delegation and devolution of regulatory powers within regulatory frameworks introduces some complexity, with an increased number of regulatory linkages and relationships, all of which are dependent on a mixture of formal or less formal contractual norms: P Vincent-Jones, "Contractual Governance: Institutional and Organisational Analysis" *Oxford Journal of Legal Studies*, Vol 20, No 3 (2000), 317 at 341.

A clear distinction is made between the pre-market conformity assessment functions set out in the directives, which are the responsibility of the manufacturers and notified bodies, and the restrictions imposed on the Member States for ensuring the appropriate surveillance of the market. Market surveillance of goods on the Community market remains the clear responsibility of the public authorities (national, regional, local and customs services) and is no part of the function of notified bodies. Indeed, market surveillance is to ensure that all the requirements of the directives have been effectively observed, not only by manufacturers and importers but also by notified bodies. An important continuing function of the Commission is to monitor the operation of notified bodies and enforcement agencies, to ensure that they operate consistently in all Member States.

Practical issues

Variations in the quality of operation by notified bodies as a whole has been a major concern emerging from the operation of the New Approach.[139] Criticisms are evident from a number of sources. This has been perhaps the major issue raised by the USA in the context of negotiations over Mutual Recognition Agreements between the USA and the EU.[140] There has been critical comment on both the performance of notified bodies and the performance of Member States in accreditation[141] and ongoing assessment.[142] For example, it has been said under the machinery Directive that:

> "it is important that authorisation to carry out assessments be withdrawn from bodies which have repeatedly issued certificates for machinery which does not meet fundamental health and safety requirements, and that the Member States be required to report such cases to the Commission."[143]

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139 In complex regulatory systems that involve the attainment of regulatory objectives through complex inter-relationships with political and social exchanges, the level of cooperation (or "compliance") is dependent on the quality of the norms and the extent of their observance (one aspect of the theoretical concept of "responsiveness"), so that where the norms are damaged or not observed, the regulatory effectiveness will decrease; the state has a role of central importance in ensuring that the norms are respected: see I Macneil, "Values in Contract: Internal and External" (1983) 78 *Northwestern University Law Review* 340; I Macneil, "Power of Contract and Agreed Remedies" (1962) 47 *Cornell Law Quarterly* 495; and P Vincent-Jones, supra at 349.

140 The traditional approach in the USA has been for the regulatory agency (FDA) to exercise sole control, operating in an authoritative manner, and third part review was unknown until introduced for low- and moderate-risk medical devices in 1996 and codified in the Food and Drug Administration Modernisation Act 1997: C Klasmeier and G Castle, "Third-Party Review" (*The Regulatory Affairs Journal (Devices)*, 2000) May, 102.

141 Communication from the Commission: Enhancing the Implementation of the New Approach Directives, COM(2003) 240, 7.5.2003, para 2.2; *Consultation Document Prepared for the Directorate General for Enterprise on the review of the New Approach* (European Commission, 2001), section 2.3.2: "the procedures are not always observed by the notifying authorities".

142 *Consultation Document, supra*, section 2.3.5.

143 Opinion of the Economic and Social Committee on the "Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC" 2001/C 311/01, OJ C 311/1, 7.11.2001.

Similarly, considerable concern was expressed in relation to variations in the general level of competence of notified bodies in relation to medical devices.[144] This led to closer scrutiny by the competent authorities through individual inspections and coordination through the establishment in 2000 of the Notified Bodies Operations Group.[145] The Study on the Low Voltage Directive similarly noted criticisms of notified bodies by competent authorities, including individuality of operation, and called for mechanisms for co-ordination and for expert accreditation of notified bodies by a member of the European Co-operation for Accreditation group and for the introduction of agreed procedures.[146]

The Commission has recognised that Directives do not provide practical guidance on how the principles of co-operation among notified bodies and other aspects of their operations, and Member States have developed differing procedures and criteria on designation and assessment of notified bodies, commenting that "a decentralised system can only work effectively if all stakeholders have full confidence in the technical competence and professionalism of all notified bodies if it is based on transparent procedures."[147] It recognised that there had, until recently, been no systematic exchange of information concerning the criteria and procedures for assessment and surveillance of notified bodies, and that this lack of transparency had encouraged suspicions about uneven levels of competence, which had undermined confidence in the system. Accordingly, the Commission has proposed to consolidate the requirements that notified bodies have to fulfil, and to form joint working groups of national officials.[148] It is also establishing a permanent forum of national authorities to exchange best practice on accreditation.[149] An information exchange is also to be established amongst notified bodies that would record those products that have been submitted for testing but been found to be non-compliant, so as to tackle multiple applications and encourage consistency of standards.[150]

STANDARDISATION

Technical directives generally provide that Member States shall presume that a product which is in conformity with the relevant national standards adopted pursuant to the harmonised European standards, the references of which have been published in the Official Journal of the European Communities, comply with the essential requirements of the directive. In drawing up European

144 Communication from the Commission to the Council and the European Parliament on medical devices, COM(2003) 386, 2.7.2003. This notes that various notified bodies have had notification revoked.

145 See Notified Body Operations Group Report for the period to 31 December 2002, March 2003.

146 A H Powell, *Study on the Implementation of the Low Voltage Directive* (European Commission, 1999) paras 5.5.8, 9.2.7.

147 *Consultation Document*, supra, section 2.3.3.

148 Communication on Enhancing the Implementation, supra, para 2.2.

149 Ibid.

150 Ibid.

standards, the Commission is assisted by the Committee on Standards and Technical Regulations established by Article 5 of Directive 83/189/EEC.

European standards therefore play a very significant function in the regulatory system of the New Approach, and in product safety. They are developed in respect of each directive in order to provide manufacturers with a set of technical specifications[151] recognised in the directive as giving a presumption of conformity to the essential requirements. Use of European standards remains voluntary: manufacturers are able to put on the Community market products which either meet other standards or no standards at all, subject to fulfilling the procedures for assessment of conformity laid down by the Directive.[152]

The use of standards is seen as being advantageous for a number of reasons.[153] Standards can provide extensive technical specifications which, if they were to be included in legislation, would not only greatly extend and complicate the legislation, turning it from statements of general principle (the essential requirements) into a mass of mandatory and detailed rules, but would also restrict innovatory or alternative means of complying with the essential requirements. Standards can be easily modified to reflect technological development.[154] Standardisation is a highly transparent process involving extensive involvement of interested parties,[155] with the ability to reflect the technological "state of the art". Most of the costs of producing technical specifications are borne by the private sector[156] and many sources of expertise are available. European standards are increasingly used for public procurement, which accounts for about 15% of the Community's gross domestic product. It is official policy that wherever possible, global harmonisation should be the objective and the Community should have recourse to international standards.[157] CEN, CENELEC and ETSI (which usually take between 2 and 3 years to deliver a standard) are in increasing contact with international bodies, including the International Standards Organisation (ISO) and the International Electrotechnical Commission (IEC). The Commission has been concerned to co-ordinate the

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151 N Brunsson, B Jacobsson and Associates, *A World of Standards* (Oxford, 2000), describe standards as expert knowledge stored in the form of rules 41.

152 Commission Communication on the development of European standardisation dated 16 October 1990, OJ No. C 20/1, 28.1.91.

153 Council Resolution of 21 December 1989 on a global approach to conformity assessment. OJ 1989 No. C 10/1, 16.1.90.

154 In contrast, amendment of the "technical specifications" for test data required for medicinal products under the Annex to Directive 75/318/EEC requires an amending Directive (91/507/EEC).

155 The European Association of Consumers involved in Standardisation (ANEC) plays an important role, although suffers from limitations in access to technical expertise and constraints on funding. N Brunsson et al, supra, note however that it is difficult to identify everyone involved.

156 Standardisation is a privatisation of rule-making, at least to the extent that sufficiently clear and extensive essential requirements are specified in the governing technical Directives: K Armstrong and S Butler, *The governance of the Single European Market* (Manchester, 1998), p 152.

157 In particular, through the Global Harmonisation Task Force, http://ghtf.org. The study group that deals with medical device vigilance, for example, has produced guidance documents on *Manufacturer's Trend Reporting of Adverse Events* (SG2-N36R7) and *Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports* (SG2-N33R11).

European standardisation organisations and has established a common consultative body, the European Standardisation Forum. This generally unified European approach contrasts with the fragmented approach in the United States of America where there are about 400 active standardisation bodies. A common mark of conformity to European standards may be introduced to replace national marks.

The Study on the Low Voltage Directive commented with approval on both the commercial and safety aspects of standards in that sector:

> "The existence of product standards has been crucial to the success of the Low-Voltage Directive in promoting barrier free trade throughout the European Community and in international markets. These standards have also enabled electrotechnical products to reach the high levels of safety achieved in the sector."[158]

There are, however, negative aspects of standardisation. The heavy reliance on expert knowledge has been criticised as lacking in democratic transparency and leading in practice to competition amongst companies.[159] The increasing length and complexity of standards means that manufacturers need sufficient understanding in how to apply them.[160] Some authorities also considered that the existing framework fails to provide the Commission or Member States with any effective means of determining whether or not a harmonised standard fully takes into account the safety requirements of the Low Voltage Directive or provides a means of challenging a standard before publication.[161] Delay over the production of standards has been extensively criticised, not least because the pace of technological change requires speedy production and updating of standards.[162]

The fact that compliance with a standard carries a legal presumption of conformity with regulatory requirements in effect places the burden of challenging the marketing of a product on safety grounds on the authorities,[163] and emphasises the importance of market surveillance and testing facilities.

The objection of an absence of consumer involvement in the process of standards drafting may have more theoretical than practical substance. The content of standards is often highly technical and requires expert knowledge of technology and practice in the particular sector. Accordingly, experts are best qualified to draft them. Experts inevitably come predominantly from industry, although academics and consultants are also involved. The involvement of personnel from competitors or companies making different products within the same sector may produce

158 A H Powell, *Study on the Implementation of the Low Voltage Directive* (European Commission, 1999), section 3.
159 N Brunsson, supra, 47-49 identifies issues of depoliticisation, technicalisation, and regulation without responsibility.
160 Powell, supra, section 5.2.4.
161 Ibid, section 5.5.9.
162 A Baxter, "Driving down the fast track", *Financial Times* November 30 1998.
163 Ibid, section 5.5.3.

uncompetitive results but may equally give some degree of objectivity, depending on the circumstances. Similarly, highly harmonised standards are both mandated and approved by the Commission.[164] A pragmatic point is that significant involvement of non-experts from whatever background in the drafting and approval process would further complicate and delay a system which is already so overloaded that its ability to continue producing standards would become questionable. The underlying objection here is that a standard might be influenced by industry so as not to set the best or optimal level of practice. Ultimately, this issue is not of great significance, since observance of standards does not guarantee or pre-empt compliance with the legal requirements, and the legal presumption of compliance is rebutable. The argument for a greater level of independent involvement is stronger in the legislative process than it is in the standards-making process, whether this be through formal representation of consumers or any other constituency which is not expert or directly involved in the subject matter.

That the Community still has confidence in the standardisation methodology can be seen by two factors: firstly, the incorporation of this mechanism into the 2001 revision of the GPSD for consumer products[165] and, secondly, the increasing use of international standards to replace Community or national standards.[166]

SOME SPECIFIC DIRECTIVES

In parallel with its generic review of the New Approach system, the Commission has recently carried out reviews of several vertical Directives, and several points concern the Directives' safety regulation of safety. In addition to significant concern over the level of competence and lack of uniform practice of notified bodies, the Report on the Medical Devices Directives[167] noted the following concerns: the level of competence of some manufacturers in producing clinical evaluation data, in design control and in conformity assessment; a need for traceability of devices, particularly implants; improvements in vigilance reporting; and investigation and greater involvement of national authorities in standardisation. A strong need was also expressed for national authorities to devote greater human and other resources to the sector.

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164 The Commission refused to accept CEN's draft of the standard on labelling of medical devices, which it considered to be not in accordance with the essential requirements.

165 Directive 2001/95/EC, articles 3.2 and 4.

166 For example ISO 9000 in place of EN 29000. See *Improving International and European Healthcare Standardization to meet Global Safety, Regulatory and Market Need: Towards a Global Strategy – Proposals for Action*, EUCOMED, 21 August 2002.

167 Communication from the Commission to the Council and the European Parliament on medical devices, COM(2003) 386, 2.7.2003.

Proposals to amend Directive 95/16/EC on machinery[168] covered many substantial amendments on technical matters[169] but was not directed at safety concerns and included no statistics on safety issues, which may indicate that safety was not thought to be a core issue with machinery. While the second recital in the revision asserted that "The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and construction"[170] no evidence was produced to substantiate the assertions relating to the number of accidents, causation, social cost or avoidance.

The 1999 Study on Directive 73/23/EEC on Low Voltage products (the "LVD")[171] noted that there was no evidence that there had been an increase in the number of accidents since the introduction of CE marking, but both the competent authorities and Community-based manufacturers were finding an increasing number of unsafe products imported from non-Community countries that failed to comply with the safety objectives of the LVD.[172] In response, industry suggested that the problem was due to the fact that the products originate in countries where manufacturers have very little experience of designing products to conform to safety standards.[173] Although the incidence of deaths due to fire and electrocution involving products remained "very low" (attributed to the development of standards and the subsequent introduction of CE marking), there was said to be cause for concern if the level of non-compliant products entering the market was not controlled.[174]

The issue that was highlighted, therefore, is one of ensuring that the market surveillance mechanisms are sufficiently robust, but inadequacies were also identified here. Firstly, the LVD contains no provisions relating to market surveillance, and it was suggested[175] that a new Article should be introduced, following a precedent in the Toys Directive.[176] However, the latter is only a general description of market surveillance and the limited scope of this proposal contrasts with the far more extensive post-marketing obligations introduced subsequently into the GPSD.[177] Secondly, the authorities faced a considerable problem in tracing the chain of supply of products originating

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168 *Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC*, COM (2000) 899 final, 2001/0004 COD; *Amended proposal* COM (2003) 48 final. This followed the *Report of the Group of Independent Experts on Legislation and Administrative Simplification*, SEC (95) 2121, 29.11.1995 (Molitor Report).

169 Both the need for a revision at that point and whether the changes would result in simplification or merely introduce greater complexity and hence opportunity for confusion were questioned: Opinion of the Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC, 2001/C 311/01, OJ C 311/1, 7.11.2001; *Revision of the Machinery Directive 98/37/EC*, ORGALIME, 11.05.2001.

170 Proposal, supra.

171 A H Powell, *Study on the Implementation of the Low Voltage Directive* (European Commission, 1999).

172 Ibid, sections 5.5.4, 9.1.

173 Ibid, section 5.4.6.

174 Ibid, section 5.5.4.

175 Study, supra, section 5.5.5.

176 Directive 88/378/EEC, article 12.

177 See chs 11 and 12.

outside the Community and identifying their importers and manufacturers.[178] It was mooted that manufacturers should appoint an authorised representative and/or state the details of the importer on the label,[179] although it may be commented that this might not succeed in giving the necessary information for parallel imports. Thirdly, there was criticism of significant differences of approach to market surveillance between Member States and it was noted that an administrative co-operation group had recently been established to tackle this issue.[180]

The competent authorities also considered that there was a problem over non-conformity of electrical products and that a significant number of manufacturers who have the capability to design and manufacture innovative products do not have the necessary resources and experience needed to ensure a safe product.[181] Some Member States were strongly of the view that, in view of the serious risks that may be associated with electrical products, third party approvals, which some Member States had traditionally supported, should be made mandatory, but the consensus view was that this should not be mandatory for products that complied with harmonised standards.[182]

CONCLUSIONS

New Approach Directives conform to a general template but individual product sectors can contain significant variations in the extent of the legal requirements. For example, the brevity of the essential requirements of the Directives on toys or low voltage can be contrasted with the length and complexity of those dealing with machinery or medical devices. The ostensible reason for this variation is the need to take an individual approach to the types of risk that are presented by particular products. For example, toys, unlike some medical devices, would not normally be expected to include sources of radiation or need to include labelling instructions on decontamination.

At the theoretical level, New Approach Directives can be seen to be difficult for operators and consumers to understand, and complex in operation. Issues of consistency, transparency and democratic accountability arise in the context of the creation of standards, the application of conformity assessment procedures to products by individual manufacturers, the operation of notified bodies, the surveillance of notified bodies by national competent authorities, and the achievement of effective market surveillance by national authorities.

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178 Ibid, sections 5.2.5, 9.2.9.

179 Ibid, section 6.7.

180 Ibid, section 7.1.

181 Ibid, sections 5.5.1, 6.3.

182 Ibid, section 5.5.1. It was argued that Module A (manufacturer's self-declaration) should be removed and that Module B (EC Type examination) should be made mandatory. It was noted that there had been a significant fall in deaths and injuries associated with electric blankets after the introduction of such a mechanism through legislation in the UK in 1971, and that third party involvement had ensured that a database was established that permitted attention to be focussed on specific types of design or product: para 6.3.

The focus of the New Approach system has essentially been on pre-marketing requirements, since compliance with essential requirements has been considered to be satisfactory from the safety perspective. The safeguard clause mechanism has always existed but has received little emphasis until post-marketing mechanisms became higher profile with their inclusion in the 2001 revision of the GPSD and with contemporaneous evidence of some problems arising from reviews of New Approach Directives. The extent to which market surveillance mechanisms will develop in New Approach Directives is unclear.

An interesting issue, which is discussed further below, arises out of the suggestion from Germany in the draft Report of national experts, but which was excluded from the subsequent Commission's Report, that a number of the difficulties identified could be solved by creating an efficient central decision-making structure such as a European Authority for Medical Devices,[183] which would have the following tasks and responsibilities:

- decision-making in safeguard clause procedures;
- decision-making about the need for a uniform procedure in the EEA as a whole in the event of national safety measures that have not led to a safeguard clause procedure;
- checking of standards prior to their citation in the Official Journal;
- drawing up of common technical specifications (as deemed necessary) and guidelines in agreement with the parties concerned;
- final say in controversial demarcation and classification questions;
- carrying out of checks under Mutual Recognition and PECA agreements;
- assisting the Commission in international matters (GHTF, WHO etc.)
- provision of scientific and regulatory advice for the Commission, national authorities and groups of specialists.

At the practical level, there is evidence of concerns over the consistent operation of notified bodies, and hints over inconsistencies by competent authorities, for example over failure to denotify notified bodies and over general market surveillance. Significantly, a UK Health Minister publicly warned that patients could die unless more national authorities devoted more resources to medical device regulation.[184] However, little evidence has emerged, whether from the Commission's reviews of the New Approach or of individual Directives or elsewhere, that products that are subject to the New Approach give rise to

183 An earlier call was Anon, "French call for EC medical devices agency" *Clinica* 1997 63;10.

184 "UK warns unsafe medical devices could kill Europeans" *Reuters*, 21 September 2001.

significant safety issues. The evidence, which will be discussed further in chapter 17 below, is that the sector where safety issues are greatest is that of consumer electrical products, but relating far more to exports than goods produced in the Community.

6. BIOCIDES, COSMETICS, TOBACCO AND GENERAL CONSUMER PRODUCTS

This chapter examines the regulatory systems for four further individual product types. Three of the types are vertical (biocides, cosmetics and tobacco) and one (the only one of its type in the field of Community product regulation) is horizontal, covering all consumer products. Each of these systems contains different provisions, but which contrast with the other regimes. The mechanisms that emerge from this and the preceding chapters revolve essentially around, first, whether primary responsibility for ensuring product safety is placed on individual manufacturers or on competent authorities and, secondly, whether the individual controls that are specified bite in the pre-marketing or post-marketing phases.

Biocidal products

A biocidal product contains one or more substances intended to act against a harmful organism by chemical or biological means, such as a disinfectant, preservative or insecticide.[185] The regulatory regime for placing a biocide on the market has strong similarities to that of medicinal products, in that it requires an authorisation to be issued by a national competent authority.[186] However, a simplified approval system is based on published lists of approved substances. Alternatively, applicants must submit a dossier that establishes that the product is sufficiently effective and has no unacceptable effects.[187] An abbreviated dossier may be submitted for low-risk products,[188] or authorities may establish a frame-formulation of specifications for a group of products.[189] The marketing of active substances for use in biocides is also restricted.[190]

Dossiers are evaluated on the basis of core principles, which include a risk assessment of the product, based on estimation of the incidence and severity of adverse effects likely to occur.[191] National authorisations must be mutually recognised by other Member States, which must grant authorisations within specified time-limits.[192] A Member State may operate a "safeguard clause" procedure and ban a biocide where it constitutes an unacceptable risk to human or animal health or the environment, and the State shall inform the Commission and the other Member States, giving reasons, after which a concerted decision procedure applies.[193]

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185 Directive 98/8/EC, article 2.1(a).
186 Directive 98/8/EC, article 5. Authorisations last for up to 10 years: article 3.6.
187 Ibid.
188 Directive 98/8/EC, article 8.3.
189 Directive 98/8/EC, article 3.4.
190 Directive 98/8/EC, article 9.
191 Directive 98/8/EC, Annex VI.
192 Directive 98/8/EC, article 4.
193 Directive 98/8/EC, article 32.

Cosmetic products

The regulation of cosmetic products is based on the premise that their safety can be ensured on the basis of prior knowledge of the safety of their ingredients.[194] Positive and negative lists of ingredients are specified by the Commission, on the basis of the advice of the Scientific Committee on Cosmetic Products and Non-Food Products.[195] Nevertheless, there is a general obligation that a cosmetic product must not be liable to cause damage to human health when applied under normal or reasonably foreseeable conditions of use.[196] The manufacturer must keep specified information accessible to the competent authorities, including details of the composition of the product, the method of manufacture, a safety assessment of the finished product, existing data on undesirable effects, proof of the claimed effect.[197] There are various labelling requirements, including date of minimum durability, particular precautions to be observed in use, batch number, function of the product, and a list of ingredients.[198] Member States may operate a "safeguard clause" procedure where, on the basis of a substantiated justification, a cosmetic product represents a hazard to health, after which it shall inform the Commission and the other Member States, when there is a joint consultation.[199]

Tobacco products

Tobacco products have been the subject of particular attention within public health policy on the basis that they "have been shown to contain and emit many noxious substances and known carcinogens hazardous to human health when burnt" and that this requires the greatest possible transparency of product information.[200] However, in eliminating barriers to trade in tobacco products, the Community has chosen to approximate only the rules on the manufacture, presentation and sale of tobacco products,[201] leaving to Member States

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194 Directive 2003/15/EC, recital 6.

195 Directive 76/768/EEC, articles 4 and 5.

196 Directive 76/768/EEC, article 2.

197 Directive 76/768/EEC, article 7a.

198 Directive 76/768/EEC, article 6.

199 Directive 76/768/EEC, article 12.

200 Directive 2001/37/EC, recital 17. See also Council Resolution of 26 November 1996 on the reduction of smoking in the European Community, 96/C 374/04, OJ C 374/4, 11.12.96; Council Resolution of 29 June 2000 on action on health determinates, 2000/C 218/03, OJ C 218/8, 31.7.2000; Communication to the Council and the European Parliament on the present and proposed Community role in combating tobacco consumption, COM (96) 609 final, 18.12.1996.

201 Not discussed here are Directives 89/552/EEC banning television advertising and 92/41/EEC banning certain types of tobacco for oral use. The Court of Justice of the European Communities held that Directive 98/43/EC on tobacco advertising would be annulled as it was improperly based on Article 100a of the Treaty: Case-376/98, *Germany v European Parliament and Council of the European Union*, [2000] ECR I-8419. For the wider implications of this judgment see P J Slot, "A Contribution to the Constitutional Debate in the Light of the Tobacco Judgment", [2002] European Law Review 3 and S Weatherill, "The Commission's Options for Developing EC Consumer Protection and Contract Law: Assessing the Constitutional Basis" [2002] EBLR 497.

"the possibility of introducing, under certain conditions, such requirements as they consider necessary in order to guarantee the protection of the health of individuals".[202]

The way in which the authorities are to assess the toxicity of, and hazards posed to the health of the consumer by, tobacco products and thus to comply with the Community's policy of ensuring a high level of protection for human health, is stated to be through the use of three mechanisms: disclosure of information, maximum yields and labelling requirements. Some have called for regulation to involve an agency.[203] The Commission is invited to submit a proposal providing for a list of common ingredients authorised for tobacco products (similar to the mechanism for cosmetic products).[204] This mechanism would presumably be simpler and more economical than the current testing and notification provisions.

Disclosure of information

First, manufacturers and importers are required to disclose to the authorities a list of all the qualitative and quantitative details of ingredients and additives used in tobacco products.[205] The list shall be accompanied by a statement setting out the reasons for the inclusion of every ingredient, indicating their function and category.[206] The list is to be accompanied by the toxicological data available to the manufacturer or importer regarding the product's ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, *inter alia*, any addictive effects.[207] The list shall be established in descending order of the weight of each ingredient included in the product.[208]

The above information is to be provided on a yearly basis.[209] Member States are required to ensure the dissemination of this information by any appropriate means, with a view to informing consumers.[210] Certain confidentiality is provided for - although the extent is unclear - by the requirement that "due account shall nevertheless be taken of protection of any information on

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202 Directive 2001/37/EC, recital 3. Use of the word "guarantee" is particularly interesting, implying that the Community measures do not achieve total protection.

203 J Britton and A McNeill, "Why Britain needs a nicotine regulation agency" *BMJ* 2001; 322: 1077-8.

204 Directive 2001/37/EC, article 12.

205 Directive 2001/37/EC, recitals 22 and 23 and article 6.

206 Ibid. This mechanism is unique in EU product regulation: no other product system requires the rationalisation for inclusion of an ingredient to be provided to the authorities, although such information for CE marked products would be available to notified bodies through the manufacturers' technical files

207 Directive 2001/37/EC, article 6.1.

208 Ibid. This is a requirement to provide such data and information as is in fact available to the particular company. There is no regulatory requirement actively to seek any or further information, in contrast to either a duty under fault liability for compensation for damage caused by failure to take reasonable action, such as in failing adequately to research or monitor a product's use, or a duty arising under Directive 2001/95/EC. There may well be differences in the quantity of information available as between the manufacturing company, the importing company, and perhaps also any separate research companies (who are not covered by any similar obligation).

209 Ibid.

210 Ibid, article 6.2.

specific product formulae which constitutes a trade secret".[211] In any event, Member States are to ensure that the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields, is made public.[212] Each Member State is required to communicate all of the above data and information submitted to it to the Commission, which shall take such data and information into account in drawing up its bi-annual report on the Directive.[213]

Maximum yields

Acting on the theory that particularly harmful effects of tobacco products are caused by specific products of the combustion of tobacco (tar, nicotine and carbon monoxide) that are inhaled, the maximum yields of each of these substances or gasses are prescribed.[214] These yields are to be measured on the basis of specified ISO standards and carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States.[215] Member States may require manufacturers or importers to carry out other tests in order to assess the yield of other substances produced by their products, and in order to assess the effects of those other substances on health, taking into account, *inter alia*, their addictiveness.[216] The results of such other tests shall be submitted to national authorities on an annual basis, or less frequently if the product specifications have not varied. Member States shall be informed of changes in product specifications.[217]

Labelling

The tar, nicotine and carbon monoxide yields of cigarettes measured in the manner prescribed above shall be printed on one side of the cigarette packet in the official language(s) of the Member State where the product is placed on the market, covering at least 10% of the surface.[218]

Certain explicit warnings, as shown in Table 6, are required to be stated on packets of tobacco products. The general yield is to cover not less than 30% of the external area.[219] The printing of the

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211 Ibid.

212 Ibid, article 6.3.

213 Ibid, article 6.4 and article 11.

214 Directive 2001/37/EC, article 3: the limits are to be introduced by member states between 2004 and 2007.

215 Directive 2001/37/EC, article 4.

216 Ibid.

217 Ibid.

218 Directive 2001/37/EC, article 5.1. For interpretation of the earlier provisions of Directives 89/622 and 92/41 see Cases C-222/91, *Ministero delle Finanze v Philip Morris Belgium SA*, [1993] ECR I-3469 (Article 4(2) of Directive 89/622 provided for only one specific warning and it was held that this precluded member states form imposing additional requirements such as a second warning), and C-11/92, *Regina v Secretary of State for Health ex p Gallaher Limited*, [1993] ECR I-3545 (a requirement in Articles 3(3) and 4(4) of Directive 89/622 that warnings must cover at least a certain specified percentage of the packet was a minimum requirement and member states could impose more extensive requirements, even where that would impose more stringent requirements on national products than imported products).

219 Directive 2001/37/EC, articles 5.2 and 5.3.

specified warnings and yield indications is subject to certain requirements, including that they be in the official language(s) of the member state where the product is placed on the market.[220]

Each unit packet shall be marked in any appropriate manner by batch numbering or its equivalent, enabling the place and time of manufacture to be determined.[221] Article 5.9 states that the purpose of this provision is to ensure product identification and traceability, although recital 20 states that the purpose is so as to ensure that products are traceable for the purposes of "monitoring compliance" with the Directive. This provision is, therefore, not so much aimed at ensuring effective consumer safety through recall, which is a very rare phenomenon with tobacco products, as at identifying and discouraging counterfeiting and smuggling.[222]

The use is prohibited on product packaging of texts, names, trademarks and figurative or other signs suggesting that a particular tobacco product is less harmful than others.[223] This provision is particularly aimed at use of texts such as "low tar", "light", "ultra-light" and "mild".[224]

The GPSD provisions and the 2004 extensions

Horizontal regulation of consumer products was introduced in 1995 under the GPSD.[225] The principal obligation is beguilingly simple: that manufacturers should only place safe products on the market.[226] This duty is supplemented by duties to provide information and a range of post-marketing obligations, which are considered further at chapters 11 and 12 . The post-marketing provisions are considerably extended as from 2004,[227] most significantly through, first, the introduction of the obligation on producers and distributors to notify competent authorities of dangerous products which they have placed on the market and, secondly, measures to strengthen the obligation on and activities of member states in market surveillance and enforcement.

The 2004 extensions are based on a Commission Report[228] on the working of the 1992 Directive, which was drawn up after a survey of the rapid exchange of information system and a study on the

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220 Directive 2001/37/EC, article 5.6.

221 Directive 2001/37/EC, article 5.9. A draft of this provision provided that the batch number should be allocated in accordance with ISO standard 8243: see Common Position (EC) No 46/2000, OJ, C 300/49, 20.10.2000.

222 Tax evasion is a significant issue in view of the high tax on tobacco products: A Pierce and J Doran "MPs alarmed by evidence of smuggling" *The Times* 22 August 2001.

223 Directive 2001/37/EC article 7.

224 Directive 2001/37/EC, recital 27.

225 See C Hodges, M Tyler and H Abbott, *Product Safety* (Sweet & Maxwell, 1996); G Howells, *Consumer Product Safety* (Dartmouth, 1998); P Cartwright, 'The Regulation of Product Safety' in G Howells (ed), *The Law of Product Liability* (Reed Elsevier (UK) Ltd, 2000).

226 The exact – and more complex – meaning of this provision is analysed at ch 8.

227 See C Hodges 'A New EC Directive on the Safety of Consumer Products' *Eur Bus Law Review* Nov/Dec 2001

228 Commission Report to the European Parliament and the Council on the experience acquired in the Application of Directive 92/59/EEC on general product safety, COM (2000) 140 final, hereafter Report".

legal practical implications of the Directive had been carried out[229]. One of the principal criticisms was of the operation by Member States of market surveillance and their systems for notification and collaboration amongst themselves. However, it is striking that the Report contained no statistics on the number or prevalence of unsafe products on the market, nor the efficiency of mechanisms to deal with them.

The Report concluded that the 1992 Directive had had limited impact in practice, but that did "not necessarily mean that unsafe products [were] being placed on the market[230]. Indeed, the Commission concluded that the Directive seemed to have achieved its objective of product safety despite problems in Finland, Austria, Sweden, the United Kingdom and Germany[231]. The main issue was that transposition seemed to have had a far more subdued impact in the other (predominantly Southern) member states, which had no history of consumer product regulation, and still had no or no adequate resources or mechanisms for market surveillance or enforcement. A particular issue was that penalties had virtually never been enforced (save notably in France and the Netherlands) and most other countries considered that the applicable penalties did not have a dissuasive effect.[232]

The Commission opined that there were serious weaknesses in market surveillance under this Directive.[233] It criticised the empowerment by Member States of competent authorities as being in some cases "weak, insufficient or ineffective".[234] There was also an absence of formal requirements for arrangements for collaboration between market surveillance authorities, which should be structured and systematic: The market is unified but the surveillance is fragmented".[235] The Commission sought to establish comparable levels of performance and proceed on the basis of equivalent principles and approaches.

It accordingly extended the obligations on Member States and established the European Product Safety Network.[236] The Study did not, however, include any statistical data on the numbers or prevention of unsafe products, and no other review was undertaken to test the proportionality of the measures contained in the 1992 Directive nor the 2001 changes.

The Study had noted differences in the models for national competent authorities, the principal models being federal (Spain and Germany, with great disparities between the resources of regions), decentralised (Austria, Finland, France, United Kingdom and the Netherlands) or centralised. All

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229 *Study on Directive 92/59/EEC*, Centre du Droit de la Consommation, Université Catholique of Louvain, 2000
230 Report, IV.I
231 Ibid
232 Ibid.
233 Report fn 44 above.
234 Ibid, p19.
235 Proposal, supra, Explanatory Memorandum, p11.
236 Directive 2001/95/EC, article 10.

Member States complained about lack of resources and it was noted that this affects the ability to ensure effective monitoring of the market and technical expertise, for example, in the absence of laboratories. Differences were also noted over whether powers were held by single ministries/authorities or disseminated among several, and issues of co-ordination were noted.[237] The authors of the Study stated that professionals rarely respected their follow-up obligations (the financial obligation being so heavy that only large companies could afford to set up follow-up systems) but did respect the largely voluntary withdrawal obligation, whereas distributors were largely ignorant of their obligations. Various difficulties were found with notification systems between member states (the article 8, now 11, procedure was hardly used; practical difficulties existed over the RAPEX system; several Member States wished the Commission to be able to take a stronger, more active role, with some calls for the creation of a European Agency for the safety of non-food products) and the 2001 Directive introduced a number of changes aimed at strengthening the articles 11-13 mechanisms.

Conclusions on the mechanisms employed

The above analysis reveals considerable similarities between the basic mechanisms employed for biocides and cosmetics. Both of these systems include advance approval by a competent authority of specified substances, of which the composition, characteristics and safety effects are known and predictable, and for which manufacturing consistency is assured. In these respects, there are great similarities with the medicinal products system. Similarly, the tobacco system involves declaration to the authorities of a product's ingredients and confirmation of consistency through results of yield tests. Both biocides and cosmetics have simplified approval systems based on lists of substances that have the prior approval of the authorities. Such systems rely heavily on availability for the authorities of expert advice, which is formalised through committees. All of the systems include labelling requirements, those for tobacco products being the most prescriptive.

Like New Approach Directives, the biocides, cosmetics and tobacco Directives essentially focus their safety techniques on pre-marketing approval mechanisms, but also include safeguard clauses for the authorities to operate as a long-stop if products turn out to be harmful. In contrast, the focus of the GPSD is heavily on post-marketing mechanisms. The GPSD pre-marketing obligation only involves producers, rather than competent authorities or notified bodies, and is brief – that consumer products be safe. There are, however, extensive post-marketing obligations on both producers, distributors (who are not included in any other system save medicines), and competent authorities, which have been significantly extended in the 2001 GPSD.

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237 The Study criticised coordination in Germany, Belgium, Finland, Greece and Luxembourg.

Given that the products covered by the GPSD are, in theory, consumer products that should have the lowest risks,[238] the issue arises of why there should be a difference in approach and emphasis as between all of the vertical Directives and the GPSD over the inclusion of pre- and post-marketing mechanisms. No official answer has addressed this point. In the context of the legislation's market-related priorities, the argument might be that reliance on pre-marketing techniques is expensive and disproportionate to the safety issues involved, and that post-marketing techniques are all that is required. However, the extent of the post-marketing mechanisms that have been erected by the GPSD and its revision impose significant cost, and were enacted amidst consumer calls for greater (albeit unquantified) protection. Moreover, such cost is imposed not only on manufacturers but also on the wider category of other producers (importers, own branders), on the authorities and even on distributors. In this context, issues of proportionality remain to be considered.

Conclusions on the safety of consumer products

The number of consumer products in circulation is unknown but enormous. Extensive data is not collected on products in circulation and it may be disproportionately costly to do so, but data of this type is fundamentally relevant information and can easily be overlooked in evaluating safety. There is also no systematic attempt to collect data on safety incidents associated with general consumer products, and whether the communication methods envisaged by the revised GPSD will be effective is unclear and will be difficult to answer empirically. It may well be worth introducing mechanisms that permit the delivery of greater statistical accuracy, given that the cost to society of UK home accident injuries, of whatever cause, has been estimated at £25,000 million annually.[239]

The limited evidence reported in Appendices 2 and 4 is, nevertheless, consistent: there are few major safety issues on consumer products within the Community, and the major safety issue arises from cheap electrical imports from the Far East. This points to a need for increased border control and for education on compliance with Community/global safety legislation rather than an issue over the extent of internal Community regulatory controls. Accordingly, questions arise whether either the introduction of any further measures, or even the extensions to the system introduced by the revised GPSD from 2004 would be cost effective or increase safety.

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238 Since such product have not been thought worthy of regulation under any specific vertical Directive, and the GPSD provisions are excluded to the extent to which there exist provisions in another Directive which are directed at the same result.

239 *Valuation of home accidents: a comparative review of home and road accidents* (Transport Research Laboratory, 1996), Report 225.

PART TWO: PROCEDURAL MECHANISMS FOR SAFETY

7. INTRODUCTION

The analysis of the various individual product Directives undertaken in Part One identified a wide range of control mechanisms that are intended to contribute to the achievement of product safety. The major findings were, first, that not every such mechanism was included in each product Directive/sector: indeed, although a number of similar techniques are found in different sectors, the overall picture is one of random usage of techniques and the absence of a coherent integrated plan. Nevertheless, secondly, certain broad similarities between particular techniques can be identified. These similarities will now be used to group techniques together and hence assist in further examination. The main ways of classifying techniques are, first, whether they apply pre- or post-marketing; secondly, if pre-marketing, whether they apply to design or production phases; and thirdly to whom they apply.

This Part critically evaluates the various mechanisms that are adopted in the different vertical and horizontal product sectors, having grouped them according to the above classifications. The objective is to analyse the following points. First, what is the purpose and nature of each technique? Secondly, in which situations is each technique used – or, to put it another way, in which items of legislation is it found or not found? A subsidiary point here is that techniques are sometimes adopted in different ways or to different extents in different product sectors, or expressed in different language, in which case the aim to is identify the reason for such differences and analyse comparative effectiveness of different approaches. Thirdly, to whom are obligations applied? Fourthly, it needs to be asked how effective each individual technique is in contributing to safety. There is, regrettably, insufficient data available to answer this question, but Part Three will examine further the overall question of the effectiveness of safety regulation.

The general categories of techniques that are examined are: control of the design process; pre-marketing assessment requirements; control of the manufacturing environment and process; post-marketing requirements on producers, distributors and the authorities; and requirements of users. These mechanisms are ordered in this sequence in order to follow the chronological path in which products are designed, developed and marketed.

Some of the techniques that are analysed are relatively straightforward concepts, such as control of the manufacturing environment and process. In relation to the more complex pre- and post-marketing techniques, a theoretical framework of individual steps or requirements is suggested that might be expected to be included in regulation on the relevant topic. This framework is then adopted as a benchmark against which the requirements that exist for individual products are

compared. This comparative exercise, firstly, reveals gaps in the techniques adopted in different product sectors and, secondly, enables a "best practice" evaluation to be undertaken. The final questions are whether it is possible to identify why differences exist in the techniques that are adopted for different products, and whether it is possible to suggest improvements. Some conclusions are stated at the end of each chapter but the main conclusions from the analysis carried out in Part Two are set out in chapter 15.

8. PRE-MARKET ASSESSMENT: AUTHORISATION TO MARKET

The purpose of pre-marketing control

The purpose of pre-marketing control is to ensure that the product's design, functionality, performance and safety are sufficiently predictable and that the predicted standard of each of these aspects is acceptable. Requiring control of the safety of a product *before* it is permitted to be placed on the market is the central procedure that is both fundamental and common to safety mechanisms for all products studied. There are explicit requirements for many product types that are covered by vertical regulation, and although there are no explicit requirements for products that are subject to the horizontal GPS provisions, the impact of the GPS requirements and of product liability law makes the voluntary adoption of appropriate measures advisable if not essential.

A theoretical framework for pre-marketing safety control: The sequence of steps

If it is appropriate to adopt a pre-marketing safety assessment, what actions and processes should be undertaken in order to achieve the policy goal of safety? The following sequence of steps is suggested: (a) information collection, (b) information evaluation, (c) exercise of judgment and making a decision, (d) formal declaration of the decision and (e) retention of the information. The extent to which these steps are included in the existing legislation will be considered in the following sections. Issues of updating the information and the decision are considered in the chapter on post-marketing controls.

Important questions that need to be considered are:

(i) is all relevant information required to be included in the assessment: how much information need be provided for the assessment and by whom?

(ii) to what extent are criteria specified against which the assessment may be undertaken, or is there uncertainty or discretion?

(iii) can the criteria change and, if so, how?

(iv) is the assessment carried out by the manufacturer and/or by an independent authority and/or by a third party?

(v) is the assessment carried out by an expert?

(vi) how much information need be retained by whom as evidence of the decision and that the correct decision was taken?

(vii) how much information shall be made public on the decision, and the reasons for it or evidence on which it was taken (transparency)?

The absence of specific provisions will not be commented on under each subject, but noted in the conclusions at the end.

A. COLLECTION OF INFORMATION

Purpose

The purpose of basing a decision on appropriate information has been discussed above and is based on scientific predictability through logical assessment. The issues that arise here are (a) who has what obligations to generate or collect information, (b) what information should be collected, and (c) who should take responsibility for the accuracy of the information and should submit the collected information for assessment?

Who generates and collects the information?

The policy tensions here are between permitting maximum flexibility through access to worldwide scientific and technical data, and the prevention of reliance on fraudulent or unreliable data. The documents and particulars that are required for applications for marketing authorisations for medicinal products must be drawn up by experts with the necessary technical or professional qualifications.[240] Certain different controls exist, for example in relation to the professional qualifications of individuals who may undertake animal[241] and clinical testing[242] for medicinal products. Otherwise, no provisions in other sectors control who may, or may be authorised, to generate or obtain relevant data on the basis of which product safety assessments are made.

What information?

Medicinal products: animal toxicology and clinical trials

An application for a marketing authorisation for a medicinal product must be accompanied by[243] the results of:

- psysico-chemical, biological or microbiological tests,
- pharmacological and toxicological tests,
- clinical trials.

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240 Directive 2001/83/EC, article 12.

241 Directive 86/609/EEC.

242 Indirectly through approval of investigators by research ethics committees, as required by generally national research practice (or statutorily in France) and for data used in applications for a marketing authorisation under Directive 2001/20/EC.

243 Directive 2001/83/EC, article 8.3(i).

These requirements are very considerably amplified in the Annex to Directive 2003/63/EC and accompanying guidelines. The purpose is specifically to evaluate whether the product is likely to have adverse effects on toxicity, reproductive function, embryo/foetal or perinatal toxicity, mutagenic or carcinogenic potential, speed of absorption by or elimination through the body, and local tolerance. These headings are intended to constitute a complete code of the necessary data [244] that needs to be assembled in order to assess whether a product is safe.

Cosmetics

It is implicit that data on the qualitative and quantitative composition of a cosmetic must be assembled, as must all information enabling a safety assessment to be made,[245] but the levels of detail found in the pharmaceutical system are not specified. The cosmetics system, like that for pharmaceuticals, enables the use of starting materials which are described in a Pharmacopoeial monograph. This mechanism essentially provides a short cut to the collation by the manufacturer of extensive data on ingredients, in that it permits certain listed ingredients to be used, and bans others, on the basis of pre-existing toxicological testing and assessments which need not be repeated or documented when approved ingredients are used in particular products.

Biocides

Similarly, the approach for biocides rests on an approved list of active substances or approval of a dossier that covers the prescribed common core data set.[246]

New Approach products

In contrast, New Approach Directives do not (generally) require the collection of specific information. Instead, conformity is required with generalised essential requirements[247] which imply the prior collection of data without specifying the nature or extent of such data, leaving it up to the manufacturer how he will satisfy the requirements. Thus, although the essential requirements for

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244 A competent authority is not authorised to require particulars and documents other than those expressly listed and may not exempt an applicant from providing a particular or document required, even if it appears practically impossible to obtain that information: Case C-127/95, *Norbrook Laboratories Ltd* v *Ministry of Agriculture, Fisheries and Food* [1998] ECR I-1531.

245 Directice 76/768/EEC, Article 7a.1.

246 Directive 98/8/EEC, Article 5 and Annexes.

247 see ch 5.

medical devices comprise a complete code of issues,[248] the wording of individual requirements is teleological rather than prescriptive, as shown by the following example:

> "8. **Infection and microbial contamination**
>
> 8.1 The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.
>
> 8.2 Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.
>
> 8.3 Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.
>
> 8.4 Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method."

New Approach: control of design documentation

The achievement of good design is clearly important to the achievement of safety, as the Economic and Social Committee has recognised in commenting on proposals to revise the Machinery Directive:

> "The proposal is also of great importance with a view to reducing the social costs arising from accidents occurring in connections with the use of machinery. The number of accidents can be reduced by integrating safety considerations into the design and construction of machinery as well as by means of proper installation and maintenance."[249]

For this reason, conformity assessment modules of New Approach Directives often include controls on evaluation of product design. For example, specified technical documentation must be prepared and kept by the manufacturer of Class I medical devices to allow assessment of the conformity of the product with the requirements of the Directive,[250] including:

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248 Directive 93/42/EEC, Annex I contains headings: general requirements; chemical, physical and biological properties; infection and microbial contamination; construction and environmental properties; measuring functions; protection against radiation; information supplied by the manufacturer.

249 Opinion of the Economic and Social Committee on the `Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC' 20001/C 311/01, OJ C 311/1. 7.11.2001.

250 Directive 93/42/EEC, Annext VII, Sections 2 and 3.

- a general description of the product, including any variants planned,
- design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.,
- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operations of the product,
- the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full,
- in the case of products placed on the market in a sterile condition, description of the methods used,
- the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other devices(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer,
- the test reports and, where appropriate, clinical data in accordance with Annex X,
- the label and instructions for use.

Similar documentation is required for all Classes of medical devices. The manufacturer must certify that he has such documentation, and (except for simple, Class I devices)[251] the Notified Body must audit the data and certify that proper technical files are maintained.[252] Additionally, in respect of higher risk, Class III devices the manufacturer must submit a comprehensive design dossier for independent assessment and periodic review by a notified body.

Who takes regulatory responsibility?

The following analysis shows that each of the sectors places responsibility for pre-marketing evaluation of a product's safety on a commercial entity, with the exception of medicines, for which although commercial entities are required to hold authorisations for a product and for its manufacture, and for submitting the relevant data to an authority for approval, the safety evaluation of a product is the primary responsibility of the approving authority.

It is not always the case that products are made by those who market them: subcontracting or branding arrangements are frequently found in practice. The consistent general approach across

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251 Because Class I devices do not require the certification by a Notified Body, they are subject to the requirement of registration with a Competent Authority, so that appropriate surveillance can be undertaken: Directive 93/42/EEC, article 14.

252 Directive 93/42/EEC, Annex II, Sections 3.1 and 3.2(c) and Annex III, Section 3.

each sector is that the primary regulatory obligations are imposed on those who commercially exploit each given product, irrespective of whatever role they may have played in its manufacture or physical marketing, and such obligations are not delegable under regulatory/criminal law, although it would be good commercial risk-reduction practice for those who are primarily responsible to have contractual recourse to those on whom they in fact rely to perform any manufacturing or other activities properly. The wording of the Biocides Directive is unusual in this respect since, unlike all the others, it does not make explicit reference to any commercial entity, but the role of a commercial authorisation holder is implicit.

Cosmetics

There is considerable choice permitted under the Cosmetics Directive as to who is to keep the specified information. It may be the manufacturer, or his agent,[253] or the person to whose order a cosmetic is manufactured, or the person responsible for placing an imported cosmetic product on the Community market.[254] There may, therefore, be some confusion about who actually is to keep the specified information, particularly where a manufacturer and another are involved, and there may be some difficulty in enforcing such a diffuse obligation. In any event, the information is to be kept at the address specified on the product's required label.[255]

Medicinal products

The person who is responsible for placing a product on the market, exploiting it under his name, is required to have a marketing authorisation. In addition, the person who actually manufactures the product, whether he is the same or a different person from the marketing authorisation holder, is required to hold a manufacturing authorisation. The marketing authorisation holder must be established within the Community.[256]

GPSD

The GPSD places regulatory responsibility for consumer products on the producer of the product. The concept of "producer" is defined widely[257] and encompasses the following six categories:

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253 This term is not defined in the legislation.

254 Directive 76/768/EEC, article 7a.1.

255 Ibid.

256 Directive 2001/83/EC, Article 8.2.

257 Directive 2001/95/EC, article 2(e), which is similar to the definition of producer in Directive 85/374/EEC on product liability.

1. the manufacturer of the product if he is established within the Community;

2. any other person who presents himself as the product's manufacturer by affixing to it his name, trade mark or other distinctive mark: [258] this does not include any person whose name or mark may be on the product, but only someone who presents himself as if he were the manufacturer, usually where the name of the manufacturer does not appear;

3. a person who reconditions the product: the rationale is that he is putting into circulation what is in effect a new product and he is therefore taking responsibility for its safety;

4. the manufacturer's representative, where the manufacturer is not established in the Community: there are uncertainties over whether any formalities apply to the appointment of such a representative and over the extent of his responsibilities – the issues are discussed below in relation to the similar concept of authorised representatives for medical device manufacturers;

5. any other professional in the supply chain in so far as his activities may affect the safety properties of a product. This category is wide and includes those who would normally be distributors: the GPSD confusingly defines distributors to be only a professional in the supply chain whose activities do not affect the safety of the product. Thus, suppliers who affect the product's safety by storing the product longer than its shelf-life, or upside down, or at the wrong temperature, are made subject to the obligations of producers.

New Approach products

New Approach Directives impose the sole and ultimate regulatory responsibility for a product and the satisfactoriness of its safety on the person who qualifies as its legal "manufacturer", who is the person who places it on the market under his own name.[259]

The legal manufacturer may, however, in practice subcontract some or all of the activities of design, production, labelling, packaging and distribution, although he retains full regulatory responsibility for designing and manufacturing the product in accordance with the essential requirements that apply to it, and for the carrying out of conformity assessment in accordance with a relevant applicable procedure.[260] The legal manufacturer's name and address must usually be marked on the product and/or its required labelling.

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258 commonly referred to as an "own-brander".

259 New Approach Directives do not contain a definition of "manufacturer" other than in Directives 90/385/EEC (active implantable medical devices), 93/42/EEC (medical devices) and 1998/79/EC (in-vitro-diagnostic medical devices).

260 *Guide to the implementation of directives based on the New Approach and the Global Approach* (European Commission, 2000).

The manufacturer of a medical device may[261] appoint an authorised representative[262] in the Community to act on his behalf in carrying out tasks required in a Directive. The representative must notify the competent authorities of the Member State in which he has registered place of business of his name and address, and specified information on the reagents and products. A similar provision (which does not use the term authorised representative) applies to class I or custom-made medical devices where the manufacturer does not have a registered place of business in a Member State: he is required to designate the person(s) responsible for marketing them are who must be established in the Community.[263]

Biocides

The Biocides Directive contains almost entirely product-specific requirements and there is virtually no reference to an applicant, still less to any requirement as to any characteristics or identity, although his existence is implied.

B. EVALUATION OF THE INFORMATION

The purpose of undertaking an evaluation is to ensure that there is adequate evidence that the product can be expected to provide the acceptable level of safety when it is used. The first issue that arises is: against what criteria should the data about the product be assessed? Further issues arise in relation to the transparency of the criteria, whether sufficient data has been produced, whether the criteria are in fact adequate, and mechanisms for changing the criteria.

What criteria?

The legal tests specified in the selected sectors for the safety-approval of products are set out in Table 1. It will be seen that there is no consistent definition of the safety-approval criteria that are specified across the different sectors. No two sectors are alike in either their approach or wording, and the range of different approaches is surprisingly wide.

For example, only the GPSD adopts the ostensibly simple basic approach of requiring that a product be "safe". It then proceeds to define the term "safe product", and does so by reference to the terminology of "acceptable risk". Acceptability is also specified in relation to biocides, which must

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261 This is compulsory for an in vitro diagnostic medical device: Directive 1998/79/EC, article 10.3.

262 See *Guide to the implementation of directives based on the New Approach and the Global Approach* (European Commission, 2000).

263 Directive 93/42/EEC, article 14.2.

satisfy several heads, one of which adopts a "negative approval" approach that the product has no unacceptable effects. A negative approval approach applies to medicines authorised under the centralised system but, surprisingly, the tests under the centralised and mutual recognition systems are both different and differ from the concepts set out in their associated recitals.

GPS products

The essence of the test under the GPSD is *acceptability of minimum risk*: the questions to be decided, in each individual case, are, firstly, whether the risks of the product are the minimum risks[264] that are compatible with the product's use (a risk-utility issue), and, secondly, whether the risks are considered to be acceptable.[265] Although the producer must make this decision every time before he places a product on the market, he will be open to sanctions if the competent authorities, or the courts if the matter reaches them, subsequently take the view that the product is too dangerous. The test is ultimately, therefore, open to subjective interpretation as to whether a product is *legally* safe or dangerous. The test only relates to "normal or reasonably foreseeable conditions of use", although some misuse or abuse may be reasonably foreseeable.

The approach to controlling safety that is taken by the GPSD is, therefore, to require the *result* that a product is safe, but not to impose any procedural requirements that must be observed by producers so as to achieve this result. To some extent, therefore, the assessment of the safety of a product is carried out *after* marketing, once the product is in use and once it has come to the attention of the authorities. This is somewhat to the detriment of producers – and benefit of consumers – in that some safety issues may have arisen after marketing that will inevitably be applied with a degree of hindsight (although this is legally inappropriate).

As with all products, the existence of a subjective test that applies to individual products on a case-by-case basis may raise issues of whether appropriate decisions are being applied as to the comparative safety of different products. The GPSD provides some assistance to producers and the authorities by providing that the assessment of conformity of a product with the general safety requirement is to be carried out in accordance with a hierarchy of criteria,[266] although conformity of a product with the criteria shall not bar the competent authorities from taking appropriate measures to impose restrictions

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264 unless the product contains no risks, which is impossible.

265 For a more extended analysis of the conditions that are to be taken into account, see C Hodges, M Tyler and H Abbott, *Product Safety* (Sweet & Maxwell, 1996).

266 Directive 2001/95/EC, article 3.2 and 3.3.

on it being placed on the market or to require its withdrawal from the market or recall where there is evidence that it is dangerous.[267]

Medicines

The aim of ensuring safety, with quality and efficacy, is included as a guiding principle for the evaluation by a competent authority of the particulars and documents accompanying an application for a marketing authorisation of a medicinal product.[268] However, the provisions that apply under the centralised and decentralised systems are in fact different. Under the centralised system, Regulation 2309/93 provides:

> "Without prejudice to other provisions of Community law, the authorisation provided for in Article 3 shall be refused if, after verification of the information and particulars submitted in accordance with Article 6, it appears that the quality, the safety or the efficacy of the medicinal product have not been adequately or sufficiently demonstrated by the applicant.
>
> Authorisation shall likewise be refused if the particulars and documents provided by the applicant in accordance with Article 6 are incorrect or if the labelling and package leaflets proposed by the applicant are not in accordance with Directive [2001/83/EC]"[269].

Thus, for products that come under the centralised system, notwithstanding that the seventh recital to the Regulation states that "only after a single scientific evaluation of the highest possible standard of the quality, safety or efficacy of technologically advanced medicinal products ... should a marketing authorization be granted", the operative test is not, as might be expected, a positive approval test that the application must be refused if the product is not considered to be adequately or sufficiently safe, but a "negative approval" test: provided the applicant submits the required particulars and documents, he is *entitled* to the grant of the application *unless* it appears that the safety or efficacy have not been adequately or sufficiently *demonstrated* by him. It is unclear from this wording whether the absence of the demonstration must be subjective to the authority or objective, in the latter case being susceptible to judicial review: however, the Court of Justice may be expected to adopt a similar approach here to that which it has taken in interpreting the provisions on suspension of marketing authorizations, where

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267 Directive 2001/95/EC, article 3.4.

268 Regulation 2309/93, article 11 and recital 3, the latter stating that "in the interests of public health it is necessary that decisions on the authorization of such medicinal products should be based on the objective scientific criteria of the quality, the safety and the efficacy of the medicinal product concerned to the exclusion of economic or other considerations"; see also Directive 93/39/EEC.

269 Regulation (EEC) No 2309/93, Article 11.

it has held that the authorities are only to be subject to limited judicial review on matters requiring complex technical assessments.[270]

A second point is that the quality, safety and efficacy of the product must be "adequately or sufficiently demonstrated" by the applicant, by means of the particulars and documents that he produces. Thus, the actual level of safety is not required to be known (it is in fact predicted and unknown at the time of marketing[271]) but must be sufficiently *demonstrated.* Thus, the level of safety that is required for regulatory approval is not absolute because it is not absolutely defined. Indeed, the term "safety" is not defined, and it is accepted by the authorities that safety is a relative term and that there is no such thing as absolute safety.[272]

This leads to the third point, which is that the level of safety is, in effect, defined by the matters covered in the particulars and documents that are required to be submitted, since these record the prescribed tests and clinical trials that are required to be carried out.[273] Safety is, therefore, to be verified, first, by a prescribed list of toxicological and pharmacological tests and clinical trials, secondly, by reference to the submission of data, which establish that the prescribed series of scientific tests has been completed and, thus, that a defined corpus of information has been assembled on the product. Thus, the actual safety of a medicinal product will not be assessed against tests that are not prescribed, either qualitatively[274] or quantitatively.

It is true that there is a requirement for expert evaluation, but this only requires a critical evaluation of the quality of the product "so as to enable the reader to obtain a good understanding of the safety of the medicinal product",[275] which is in effect a statement of its comparative level of safety rather than an opinion that the product is safe or satisfies any particular test.

In contrast, the test for approval under the mutual recognition system is different. Article 26 of Directive 2001/83/EC states:

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270 Case C-120/97 *Upjohn Ltd v The Licensing Authority established by the Medicines Act 1968 and Others* [1999] ECR I-223.

271 See ch 4.

272 See ch 19.

273 Regulation 2309/93 article 9.1 provides that an application will not be granted, *inter alia*, where the opinion of the Committee is that the application does not satisfy the criteria for authorisation set out in that Regulation.

274 Thalidomide has been found to produce phocomelia in a single animal species, the New Zealand White rabbit, but it was not tested in that species, or required to be at the time. There are ethical and economic limitations on the extent to which it is reasonable to expect pre-market testing of any product.

275 Directive 2001/83/EC, Annex I, Part 1, C; see also Article 12, which is set out at ch 8.

> "The authorisation... shall be refused if, after verification of the particulars and documents listed in Articles 8 and 10(1), it proves that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared."

It might have been expected that the legal test for marketing a product as sensitive as a medicine would be that of the positive establishment that the product is safe (which is, notwithstanding the caveats referred to above, in effect, the test under the centralised system). Whereas, the test for the mutual recognition system is a negative test, an *absence* of proof that the product is *harmful* in the normal conditions of use. It follows that an applicant is *entitled* to a marketing authorisation on submission of the prescribed particulars and documents: as with the centralised system, safety is defined by reference to the matters covered in the prescribed particulars and documents. Since the competent authority is to make its decision essentially on the basis of the particulars and documents that the applicant has submitted, one may wonder how an authority may logically be expected to "prove" in any particular case that a given product *is* harmful. Thus, under the mutual recognition system, the burden at the point of authorisation is in effect on the authority to prove the difficult proposition that a product is harmful, whereas under the centralised system the burden is on the applicant to prove that the product is adequately or sufficiently demonstrated. A further curiosity is that no litigation seems to have arisen on this point.

It is difficult to formulate a policy reason why the tests for refusal should be different under the two systems,[276] and it may be presumed that they are in fact intended to be the same, but it can clearly be argued that there are differences between the two wordings used, in particular that there is a difference between it being proved that the product is *harmful in the normal conditions of use* or that its *safety has not been adequately or sufficiently demonstrated.* The required level of safety under the centralised procedure test is not defined and is, therefore, legally uncertain, whereas the mutual recognition test not only states a supposedly objective standard but is also restricted to the normal conditions of use. No doubt there remains some uncertainty over what level of safety is "harmful" and what constitutes "normal" conditions of use.[277] The existence of different tests for the two systems is illogical.[278]

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276 There are other tests that do not differ, such as that the product's qualitative and quantitative composition is not as declared.

277 These are presumably defined by reference to the conditions of use stated in the summary of product characteristics.

278 Ultimately, the point is of diminishing importance if, as anticipated, authorisations are increasingly granted solely under the centralised system.

Under the mutual recognition system, although the operative test in the body of the Directive for authorisation is where the product "proves to be harmful", the related recital states specifies a different test, based on risk-benefit assessment:

> "The concepts of harmfulness and therapeutic efficacy can only be examined in relation to each other and have only a relative significance depending on the progress of scientific knowledge and the use for which the medicinal product is intended. The particulars and documents which must accompany an application for a marketing authorisation demonstrate that *potential risks are outweighed by the therapeutic efficacy of the product.*" (emphasis added)[279]

A risk-benefit test is applied by the authorities in practice under both the centralised and mutual recognition procedures,[280] both in the authorisation and withdrawal situations, and it is curious that such a test is neither adopted in the operative provisions of the legislation, not specified under the centralised system, [281] and that there is no consistency between the tests that are applicable in the authorisation and withdrawal stages. It is only possible to apply a more defined test of safety in the post-marketing situation, and this requires a continuous reassessment of whether the product's level of safety is acceptable, based on evaluation of the data that is available from reports of adverse events that are observed with its use.

New Approach

New Approach Directives typically specify that products must conform to their specified essential requirements. There is considerable variation in the existence and wording of essential requirements on whether products must generally be "safe": provisions are summarised in Table 1. There is also considerable variation in the length and scope of essential requirements, ranging from minimalist (toys, low voltage) to very extensive (machinery, medical devices). In general, essential requirements:

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279 Directive 2001/83/EC, recital 7. Article 102 also provides that the pharmacovigilance system shall take into account any available information on misuse and abuse which may have an impact on the evaluation of their benefits and risks, although the operative test for suspension or withdrawal of the authorisation in article 116 is the "proves to be harmful" test.

280 For example, the UK agency's consumer handbook on the safety and regulation of medicines says: "A completely safe medicine will probably never exist. Even aspirin can occasionally cause problems; safety is a relative term. When the licensing authority decides whether or not to grant a licence for a medicinal product it balances the risk from possible side-effects against the likely benefit to patients, having had advice from its advisory bodies as necessary. Therefore, a greater risk for perceived benefit may be taken for one product as against another. However, all medicines that are effective have some side-effects and should be used only when needed. The same medicinal product may affect different people in different ways.": *Towards safe medicines. A guide to the control of safety, quality and efficacy of human medicines in the United Kingdom.* HMSO. 1993.

281 Under the centralised system, the only reference to where a product "presents an unacceptable level of risk under normal conditions of use" is in a recital that applies to the power for rapid withdrawal of a product from the market: Regulation (EEC) No 2309/93, recital 15.

"either arise from certain hazards associated with the product (for example physical and mechanical resistance, flammability, chemical, electrical or biological properties, hygiene, radioactivity, accuracy), or refer to the product or its performance (for example provisions regarding materials, design, construction, manufacturing process, instructions drawn up by the manufacturer), or lay down the principal protection objective (for example by means of an illustrative list). Often they are a combination of these."[282]

By way of illustration, medical devices may only be placed on the market and put into service

"if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly [implanted/installed], maintained and used in accordance with their intended purposes".[283]

The essential requirements for devices are principally concerned at ensuring that the device is safe in use although some requirements are directed more at performance aspects. They are extensive and wide-ranging in scope, and their flavour can be seen from the following "General Requirements":-

"1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),

- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,

- inform users of the residual risks due to any shortcomings of the protection measures adopted.

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(2)(a), as specified by the manufacturer.

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282 *Guide to the implementation of directives based on the New Approach and the Global Approach* (European Commission, 2000), section 4.

283. Article 2 of Directives 90/385/EEC and 93/42/EEC: the word "implanted" appears in the former and "installed" in the latter.

4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended."[284]

Under the New Approach system, all of the essential requirements (Annex I) apply in full to every product (unless they are clearly inapplicable given the nature of the particular device). There is, however, some flexibility, since it is recognised that to place on all manufacturers the full administrative burden and cost of complying with onerous conformity assessment procedures (e.g. full quality assurance, for medical devices Annex II, or product type examination Annex III coupled with production quality assurance Annex V) is unnecessary and would force many small manufacturers of devices (which constitute a significant group) out of business and restrict the market for useful healthcare products.

What conditions of use are relevant?

To what extent is pre-marketing safety assessment under each regime limited to normal or particular circumstances of use? The approval of some products, notably medicines and medical devices, is limited to defined uses, that are specified in advance by the manufacturer. In contrast, the tests for cosmetics and GPSD products are wider, in that these products must be safe not only in their normal conditions of use but also in reasonably foreseeable conditions of use.

A medicinal product is authorised in relation to specified therapeutic indications of use that are set out in the summary of product characteristics,[285] which must also include conditions such as the maximum recommended safe dose, duration of use and any known contra-indications, interactions or special warnings. Pre-marketing assessment of a medicine is limited to evaluation of the data that is available from the tests and trials that are prescribed, although post-marketing assessment will take into account data that emerge on misuse and abuse.

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284 The other headings for requirements are listed at fn 8 above.

285 Directive 2001/83/EEC, article 11.

The safety of a medical device is only to be assessed in relation to foreseeable, normal use under conditions of intended use specified by the manufacturer.[286] The essential requirements provide that:

"- when used under the conditions and for the purposes intended", the device will not compromise the clinical condition or the safety of patients, etc,[287] and

- the characteristics and performances must not be adversely affected when the device is subjected to the stresses which can occur during *normal* conditions of use.[288]

A cosmetic must not be liable to cause damage to human health when applied under *normal or reasonably foreseeable* conditions of use, which is limited by the product's presentation (ie its stated purpose)[289]

However, the assessment of safety of a consumer product under the GPSD is based on the "normal or reasonably foreseeable conditions of use including duration" and this test does encompass situations of misuse and abuse where these are normal or reasonably foreseeable.[290]

C. EXERCISING JUDGMENT IN MAKING A DECISION

The central question here is who should make the decision: should it be the person responsible for marketing the product, or an independent regulator, or someone else? In any event, should the person satisfy any criteria, such as in relation to expertise or independence? To what extent may or must the decision-maker rely on independent expert advice?

Who decides?

There is a most striking difference here between different product sectors. The authorisation decision is taken by a competent authority for a medicinal product and, unless the active substances are on a list approved by the authority, for a biocide,[291] whereas for every other product type it is taken by the manufacturer. In constitutional terms, the manufacturer might be considered as having authority delegated to it by the state. There is, however, some blurring between these two extreme positions.

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286 Directive 93/42/EEC, Article 2 refers to compliance when properly installed, maintained and used in accordance with their intended purpose.

287 Directive 93/42/EEC, Annex I, para 1.

288 Directive 93/42/EEC, Annex I, para 1.

289 Directive 76/768/EEC, article 2.

290 Directive 2001/95/EC, article 2(b).

291 Directive 98/8/EC, Article 5.

GPS products

It has been noted above that the decision on compliance with the general safety requirement for consumer products that are subject to the GPSD implicitly rests with the producer of the product,[292] but that there are no procedural requirements.

Medicinal products

Although the legal decision is taken by the Commission in the case of medicines within the centralised procedure, or by a national authority in the case of those subject to the decentralised procedure, the technical evaluation is undertaken by a committee of scientific experts:[293] formally, their function is purely advisory but in practice their decision is almost always conclusive. Indeed, it is thought that there has not been a case where the Commission has differed from the advice of the Committee on Proprietary Medicinal Products.[294] The delay to the issuing of an authorisation caused by the need for two organisations rather than one to be involved, and particularly the Commission's delay in processing the issue of authorisations, have been criticised by industry as delaying commercialisation while patent protection continues to erode, but can also be criticised as delaying availability of products to patients.[295]

Experts employed or consulted by the manufacturer also have an important role. Reports are required from experts in analysis, pharmacology and clinical trials.[296] These reports fulfil two functions[297]: first, verification that the relevant tasks have been carried out and the results are described objectively; secondly, to describe their observations in accordance with the requirements of Directive 2001/83/EC and to state, in particular:

> "- in the case of the analyst, whether the medicinal product is consistent with the declared composition, giving any substantiation of the control methods employed by the manufacturer;

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292 Directive 2001/95/EC, article 3.1.

293 It can be strongly argued that the members of the CPMP are insufficiently independent of political and governmental influences. There is no requirement for independence: the members are nominated by Member States and have always been physicians who are employed by the Member States' medicines agencies rather than practising clinicians. Evaluations are in theory undertaken personally but in fact by the agencies to which each member is attached.

294 A decision in 1982 by Secretary of State Kenneth Clark MP to refuse a licence to Depo-Provera, an injectable contraceptive manufactured by Upjohn Ltd, led to a threat by the members of the Committee on Safety of Medicines, who had recommended approval, to resign en masse.

295 CMS Cameron McKenna and Andersen Consulting, *Final Report: Evaluation of the operation of Community procedures for the authorisation of medicinal products* (European Commission, 2000).

296 Directive 2001/83/EC, Article 12 and Annex, Part 1.C; Regulation (EEC) No 2309/93, Article 6.

297 Directive 2001/83/EC, Article 12; Regulation (EEC) No 2309/93, Article 6.

- in the case of the pharmacologist or the specialist with similar experimental competence, the toxicity of the medicinal product and the pharmacological properties observed;

- in the case of the clinician, whether he has been able to ascertain effects on persons treated with the medicinal product which correspond to the particulars given by the applicant in accordance with Articles 8 and 10, whether the patient tolerates the medicinal product well, the posology the clinician advises and any contra-indications and adverse reactions".

The functions of the experts are further clarified in the Annex to Directive 2001/83/EC:

> "The expert report shall consist of a critical evaluation of the quality of the medicinal product and the investigations carried out on animals and human beings and bring out all the data relevant for evaluation. It shall be worded so as to enable the reader to obtain a good understanding of the properties, quality, the proposed specifications and control methods, the safety, the efficacy, the advantages and disadvantages of the medicinal product...."[298]

Cosmetics

Although the manufacturer of a cosmetic has sole authority and responsibility to decide to market a product, his freedom of action is circumscribed by the requirement to use only ingredients listed as approved by the Scientific Committee.

The manufacturer of a cosmetic must keep readily accessible to the competent authority the assessment of the safety for human health of the finished product, undertaken by a qualified person, who must hold a diploma in pharmacy, toxicology, dermatology, medicine or a similar discipline.[299] The qualified person therefore performs the single and crucial function in connection with the safety assessment of a cosmetic.

New Approach products

The manufacturer of a New Approach product always has sole authority and responsibility to decide to place his product on the market. An alarmist might criticise this absence of independent scrutiny but a pragmatist or an economist would defend it on grounds of proportionality in the absence of evidence of a lack of data indicating a safety issue existing in practice. There is no requirement for a qualified person to exist or to perform any crucial function, such as undertaking a safety assessment,

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298 Directive 2001/83/EC, Annex I, Part 1, C.

299 Directive 76/768/EEC, article 7a(e).

in relation to a New Approach product. Some products, which have higher intrinsic risk, must have their design and/or production and/or quality system be certified by a notified body.[300]

D. EVALUATION PROCESSES

What processes should be undertaken in order to ensure that the data on the product have been adequately evaluated?

What processes?

There is no specification or public information on the evaluation processes that are adopted by competent authorities or their advisory committees in evaluating an application for a marketing authorisation for a medicinal product, or approval of a biocide. A risk assessment (provided by the applicant) is explicitly required for a biocide. The mode of operation and deliberations of the authorities are, unless published voluntarily, confidential, although the authorisation of individual products is published together with, in the case of medicines, a summary of the evaluation of the product.

In contrast, the New Approach requires that the manufacturer undertakes a process of the assessment of the product's conformity with the essential requirements. New Approach Directives often prescribe several conformity assessment routes, with the general intention of permitting manufacturers some degree of choice. No further details are, however, specified as to what this procedure involves. The requirement implies that the manufacturer should keep a control document which records what evidential data the manufacturer has considered in coming to his judgment that each essential requirement is satisfied[301]: many manufacturers find the absence of a specific requirement to keep such control documentation confusing in understanding exactly what it is they have to do.[302] A requirement for such documentation would assist in achieving safety by directing manufacturers' minds towards their need to conclude that every essential requirement has in fact been satisfied. The same can be said

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300 The functions of notified bodies are examined in chapters 5 and 17. Some Directives use other terms: an inspection body (simple pressure vessels and construction products), a testing laboratory and a certification body (construction products) or an approved body (toys). A competent body under Directive 89/336/EEC on electromagnetic compatibility performs a similar purpose to a notified body and the Commission considers that the same principles apply: *Guide to the implementation of directives based on the New Approach and the Global Approach* (European Commission, 2000), 6.1.

301 see standard documentation recommended by EUCOMED for compliance with Directive 93/42/EEC.

302 Numerous conversations between the author and manufacturers.

in relation to undertaking a risk assessment on each product: this may be implicit in relation to many product sectors but is rarely explicit.[303]

For cosmetics, the approval process is in effect based on a bifurcated system. First, listing of approved or banned ingredients, together with their concentrations and labelling requirements, is an official process undertaken by the European Commission on the advice of its relevant Scientific Committee. Secondly, a manufacturer assembles his own Product Information File that contains specified information, of which the most important is a safety assessment on the finished product by a qualified person.

No processes are specified for consumer products under the GPSD, although it is arguable that undertaking a risk assessment is implicit.

E. FORMALITIES OF THE DECISION

What procedural mechanisms should be required in order to formalise the fact that a decision has been taken that the product is sufficiently safe to be marketed? The purposes in requiring a formal step to be taken are (a) to promote safety by requiring that the decision maker directs his mind to the assessment of all the prescribed matters relevant to the safety of the product before it is released for use, in relation to assessment of both each matter individually and the overview of the product's safety, (b) to provide public evidence of such formal assessment, both so as to afford public confidence that the product's safety has been assessed and found to be satisfactory, and (c) to provide a record of the decision, the information on which it was based and the reasons for taking it, in case there should subsequently be a need to examine these matters, for example if any of them should later be updated or are questioned.

What formalities?

For medicines, a marketing authorisation granted by the competent authority is a formal document incorporating reference to conditions with which the holder must comply, on matters such as labelling and maintenance of a post-marketing vigilance system. Each decision is published by the authorities[304]

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303 It is required for machinery and arguably for medical devices, and harmonised standards exist for both these sectors: see ch 19, fn 76.

304 in the *Official Journal of the European Communities.*

and the manufacturer must include the unique marketing authorisation number of the product on its labelling.[305] Authorisation by an authority also applies to biocides.

For New Approach products, the manufacturer signs and keeps a declaration of conformity of his product with the essential requirements.[306] If he is required to have the approval of a notified body to an aspect of his system, design or production, the notified body should previously have issued the manufacturer with a signed certificate of compliance. The public sign of the decision is the CE marking that the manufacturer is permitted and required to place on the products.

For cosmetic products, there is no requirement to draw up a declaration of conformity or an equivalent document. An equivalent function is, however, performed by the requirement to have available the information prescribed in Article 7a of Directive 76/76/8/EEC, particularly the qualified person's safety assessment. Similarly, there is no requirement for a public symbol, such as CE marking.

The same is true for consumer products: the GPSD specifies no pre-marketing procedures or public symbols. If the three rationales, set out at the start of this section, for requiring public evidence of formality of approval hold good for any product sector, there is clearly an argument that they hold good for all product types. The counter-argument that such a step would involve disproportionate cost is of little weight. It is, therefore, difficult to see why CE marking should not be standard for all Community products.

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305 Directive 2001/83/EC, Article 54 (l).

306 see standard EN 45014 for general criteria for a declaration of conformity.

F. EVIDENCE RETENTION

The issues that arise here are, first, what data should be kept so as to provide satisfactory evidence of the original decision and how it was reached and, secondly, for how long. The purpose is to provide evidence of and justification for the foundation for the marketing decision, in case these matters should subsequently be questioned or need revision.

For how long are approvals valid?

There are no specifications for cosmetics or for GPS products. The following periods are specified:

- medicines: a marketing authorisation is valid for five years (renewable).[307]

- new approach: decisions taken by a notified body on medical devices in Annexes II and III are valid for a maximum of five years.[308]

It is unclear what length of production New Approach manufacturers' declarations of conformity may cover: this seems to be left for individual preference and has caused confusion in practice. One argument is that, as with cosmetics and GPS products, it is satisfactory for a product of this type, for which the risks should have been identified in advance and assessed to be acceptable, to continue to be made (by the same process and to the same specification) and marketed as long as there is no further evidence that its safety profile is more adverse than was at first thought. The alternative argument is that a requirement that the manufacturer should periodically confirm that he holds the necessary data and has reassessed the product's safety may be appropriate. Evaluating the strengths of these two arguments itself requires a risk assessment and cannot be completed without empirical data.

Who keeps what and for how long?

Since these aspects are obligations that apply in the post-marketing situation, they are discussed at chapter 11.

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307 Regulation (EEC) No 2309/93, article 13: it is proposed that this period should be indefinite, subject to more regular pharmacovigilance reporting.

308 Directive 93/42/EEC, article 11.11.

CONCLUSIONS

The findings of the analysis set out above are summarised in Table 4. Each of the six techniques that have been considered above is found in one or more product sector and has a purpose that contributes towards achieving product safety. Thus, some sort of pre-marketing assessment process is a regulatory requirement for all of the product sectors studied, although there are considerable differences between the sectors. Do these differences matter? It seems fairly clear that one approach does not fit all products. Thus, the predominant approach for engineered products made from materials rests on control of design, supplemented by risk assessment. In contrast, the approach for products that comprise chemical substances relies on knowledge of the predictability of the chemical or pharmacological characteristics of the particular substances, based on published experience or testing. In both cases, there is reliance on the predictability afforded by the laws of physics, chemistry and other disciplines.

Further considerations that support a pluralistic approach are the need for flexibility and proportionality, because of the need to encompass the very wide range of products, to avoid imposing disproportionately costly requirements on simple, cheap products, and so as not to stifle innovation. These considerations underlie the minimalist approach of the GPSD (simply requiring the result that a product be safe,[309] without requiring that any formal process be undertaken). Given that products that fall only under the GPSD are likely to have lower risk than products that fall under a vertical regime, it would be difficult to generalise about precise requirements that would be applicable to all possible products, given the enormous potential variation in (hopefully minor) risks that might arise from the large and different product types that are covered. In any event, some products that fall under the GPSD are partially subject to specific requirements of other Directives that control particular safety risks,[310] such as in relation to electrical or electromagnetic radiation risks.[311] The strength of this argument should be measured against safety statistics, but this has not been done.

Another feature concerns the large range of actors who have legal functions under different regimes: competent authorities, the Commission, an agency such as the EMEA, national experts, notified bodies, manufacturers and authorised representatives. Some regimes rely heavily on expert

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309 A consequence of the generalised GPS approach is that the GPS requirements are focused on producers and distributors whereas the requirements under technical directives are focused more on products, with lists of specified required tests or aspects that must be evaluated.

310 Directive 2001/95/EC, article 1.2.

311 Directives 73/23/EEC and 89/336/EEC.

assessment, whether by manufacturers' employees or consultants or by regulators and their consultants.

Despite a need for requirements that are specific to particular regimes, the above analysis does, however, show that there is little unity as between individual regimes in relation to specification of processes, techniques and wordings. For example, there is no harmonisation as to the central issue of the criteria for deciding whether a product is safe enough to market. Indeed, the range of approaches towards the fundamentally important criterion of approval of a product for marketing is alarmingly wide and inconsistent as between all sectors. This issue will be taken further in chapter 18. There does seem to be scope for increased consistency through unification of approaches between the different regimes. Overall, these are systems of considerable complexity, that raise issues of a lack of transparency and comprehensibility to an outsider.

9. CONTROL OF THE MANUFACTURING ENVIRONMENT AND PROCESS

Purpose

The objectives of control of the manufacturing environment are to ensure the quality and consistency of products that are made and that they conform to the approved design.

Mechanism

Failure of quality control procedures can occur with any product,[312] and problems arise relatively frequently over standards of preparation of food, where there are so many locations involved. Particular packing materials have sometimes been recognised as giving rise to safety concerns.[313]

It is axiomatic that products should be manufactured, assembled and packed in an appropriate and consistent environment. This is achieved by adopting Good Manufacturing Practices (GMP) or (as has become recent practice) Quality Management System Standards. The series of standards that is extensively adopted is the ISO 9000 series of 'quality' standards, that have been described as fulfilling two functions: a guarantee of reliability for the customer of the properties of the product (product quality) and/or of the system of processes by which the product is manufactured (quality system).[314] The ISO 9000 series is incorporated into the legislation for medicines and some New Approach products.

Medicinal products

The manufacture of medicinal products is subject to the holding of an authorisation granted by the competent authority in whose territory the manufacturer is located.[315] The applicant must "meet at least the following requirements" and provide particulars in support of these requirements:[316]

(a) specify the medicinal products and pharmaceutical forms to be manufactured or imported and the place where they are to be manufactured or controlled;

(b) have at his disposal for the manufacture or import suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements which the

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312 An extreme example was 53 deaths of haemodialyis patients in 2001 (including 11 in Spain and 23 in Croatia) reported to be due to the presence of residues of a toxic substance used for checking the patency of filters in dialysers, although this may have been an issue of design rather than a manufacturing defect: Anon, 'Baxter reports FDA subpoena, revises expectations', *Clinica*, 21 March 2003, 1050, 11.

313 C MacCarthy, "Cancer fears over food packets", *Financial Times*, 13 August 2001, and Anon, "Plastic wrapping contaminates food", in *Liability, Risk and Insurance*, (2001), Issue 134, p 7, which reported evidence of carcinogens leaching into foodstuffs from multi-layered heavy-grade plastic laminates used to wrap food.

314 S Furusten, 'The Knowledge Base of Standards' in N Brunsson et al, *A World of Standards* (Oxford, 2000).

315 Directive 2001/83/EC, article 40, first introduced by Directive 75/319/EEC. There are certain exemptions for products prepared by doctors, dentists or pharmacists, particularly for specified patients.

316 Directive 2001/83/EC, article 41.

Member State concerned lays down as regards both manufacture and control and the storage of products;[317]

(c) have permanently and continuously at his disposal the services of at least one qualified person who is responsible for securing[318] that the manufacturer or importer is able to carry out manufacture in accordance with the particulars supplied pursuant to the application for marketing authorisation[319] and/or carry out controls according to the methods described in the particulars accompanying the application.[320]

It is a requirement that principles and guidelines of good manufacturing practice are to be applied by a manufacturer in the manufacture of medicinal products.[321]

The scheme of the legislation, therefore, involves initial approval of facilities and controls by the authority (and may inspect the operation at any time) and a measure of delegation of regulatory responsibility to a specified qualified person, who is paid by the manufacturer but whose function is to exercise independent professional judgment in relation to batch release, thereby addressing the quality, and hence safety, of products that are produced.[322] The qualified person is required to certify in a register that each production batch satisfies the requirements, and the information must be kept available for 5 years. Official specifications are also issued for individual medicinal substances or ingredients, which define their chemical tolerances and test methodologies, which are published in the European or national Pharmacopoeias. Substances conforming to such specifications are generally required to be used for the manufacture of medicinal products.[323]

The result is that it is rare for manufacturing quality defects to arise in relation to medicinal products: the controls of the manufacturing environments and the standards that are applied are high.[324]

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317 Pursuant to Directive 2001/83/EC, article 20.

318 Ibid, which empowers an authority to permit certain variations.

319 Directive 2001/83/EC, article 8.3(d).

320 Directive 2001/83/EC, article 8.3(h).

321 Directive 2001/83/EC, article 47. The principles and guidelines that are to be applied are set out in Commission Directive 91/356/EEC, which customises "general" GMP principles for application to medicinal products.

322 These arrangements have been described by a lawyer for the EMEA (A Cuvillier, "The role of the European Medicines Evaluation Agency in the harmonisation of pharmaceutical regulation", in R Goldberg and J Lonbay (eds), *Pharmaceutical Medicine, Biotechnology, and European Law*, (Cambridge, 2000)) as self-certification, but the fact that a qualified person is responsible who must satisfy professional qualifications and discharge personal obligations is more than mere self-certification by a manufacturer, and introduces some measure of independence from the manufacturer, as can be seen by comparison with manufacturers' certification under the New Approach system discussed below. The qualified person must fulfil specified minimum conditions of qualification, including a four year university course or its equivalent, in one of the scientific disciplines of pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology or biology, plus at least two years' practical experience, in one or more undertakings which are authorised to manufacture medicines, in qualitative and quantitative analysis of, and quality testing and checking of, medicinal products: Directive 2001/83/EC, article 49.

323 Directive 2001/83/EC, Annex, Part 2.

324 The UK authority reports around 100 confirmed reports of drug defects arising a year in the UK and receiving around 140 such reports from other EU states. In 2001-02, these were regarded as sufficiently serious for the issue of Drug

Medical devices

The medical devices Directives require companies to establish quality management systems, and, for all but the lowest risk (Class I) devices, these systems must be certified as being in compliance with the relevant part of EN 29000 by a Notified Body. The European system has been further developed by adopting the new EN 46000 standards which add specific quality requirements aimed at the device industry. In both continents, regulation is based on the International Quality Systems Standards (ISO 9000 series: EN 29000 series). These have been incorporated into the FDA's Quality System Regulation which comes into force in June 1997 and which replaces its previous GMP Regulations.

Thus documented, controlled and normally certified quality systems are required, whatever Class a device falls into and whatever conformity assessment route is chosen:

Annex II, Section 3

Annex IV

Annex V, Sections 1-3

Annex VI, Sections 1-3

Annex VIII, see Section 3, second indent

Unsurprisingly, but appropriately, the degree of detail required could be said to increase as the risk classification of the device in question increases, with Annex VII for Class I devices not being as onerous as under the other Annexes. For example, under Annexes II, IV, V and VI, the manufacturer is subject to regular inspection and certification by an independent technical authority with appropriate expertise (a notified body). However, whatever the medical device involved, the environment in which its manufactured is controlled by law.

Conclusions

The need to control manufacturing processes so as to ensure consistency is self-recommending for all utility products that are engineered or comprise chemical substances, so it may be questioned why this is not a requirement for all product sectors. The New Approach model shows that a variable approach can be achieved which may not overload small manufacturers. An answer to this may be that there is no safety case to justify imposition of any further requirement than is contained in the

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Alerts in 28 UK and 4 EU cases: National Audit Office, *Safety, quality, efficacy: regulating medicines in the UK*, (The Stationery Office, 2003).

voluntary ISO 9000 series of standards: clothing and furniture, for instance, do not generally give rise to safety issues that would justify a requirement for manufacturing consistency, over and above existing commercial pressures of producing goods of consistent quality.

Such legal provisions as exist, and the ISO 9000 provisions, satisfy the parameters of clarifying who has the obligation of ensuring compliance and what the general approach is towards compliance, although IS) 9000 is expressed in broad principles that have to be applied in each situation.

Furusten identifies limited academic influence in the development of quality standards, and notes criticism of the model of reliance on management control.[325] The issue becomes in practice whether reliance on a quality system is capable of guaranteeing product quality, or, hence, safety. It remains an open question whether data-based systems are capable of ensuring that all necessary inputs and outputs are achieved.

325 Furusten, supra.

10. PROVIDING INFORMATION

The purpose of providing information

Ensuring that consumers have sufficient and adequate information on the safety of the products that they use, so that a user can take steps to avoid known hazards, has long been recognised as a central function of regulation.[326] The practical question is who has the best opportunity to prevent particular accidents: designers, makers, distributors or users?[327] Each of these categories of people have some function, although producers can be expected to have significant understanding of the risks of their products in use and how these can best be avoided, so that each user can make his or her own risk assessment. Producers may in theory market products that contain significant hazards as long as appropriate warnings are given, although risk management principles dictate that identified hazards should be designed out of products. Research demonstrates that instructions and warnings are almost always much less effective as preventive measures than design changes.[328] Market theory argues that information on safe use should be provided to users since the availability of information is otherwise shared asymmetrically. It is, however, the user who has to observe and apply the information given.[329] Communication of information from producer to consumer signifies, in non-legal terms, the transfer of responsibility for risk.

An example of information failure is the medicinal use of herbal products, which have historically been marketed without any safety information since they have been exempted from regulation under the medicinal product regime. Uninformed use of certain herbal products is known to have given rise to public health issues[330] yet claims for medicinal use cannot be made for a product without making it subject to medicinal product regulation, so the provision of information on safe use with an unlicenced product is prohibited.

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326 This is one of the core justifications for regulatory intervention based on the "market failure" theory, discussed at ch 17: see for example A I Ogus, *Regulation: Legal Form and Economic Theory* (Oxford, 1994), ch 7. Controlling information as the main tool of regulation so as to enable consumers to exercise choice in their own best interests is adopted in *Office of Fair Trading, Consumer Affairs Strategy – A Consultation Paper* (Office of Fair Trading, 1996) which also recognised that it is rarely clear how much or what information it is efficient for consumers to obtain.

327 G Hayward, 'Domestic and personal accidents: Prevention in the absence of professional supervision', *Accident Analysis and Prevention* 32 (2000) 329-335.

328 D Lucas, 'Warnings: do they really make a difference?' *Safety and Health Practitioner* (1999) 17 (7), 18-19.

329 It is, therefore, incumbent on users to take responsibility for using products in accordance with the information provided and with common sense so as to avoid accidents, as discussed in ch 14, and this is underpinned by the evidence that users' behaviour is responsible for many accidents, discussed at ch 6. Users' failure to act sensibly will bar their ability to recover for product liability but is not generally covered by regulatory obligations.

330 For example, St John's Wort has been widely used for self-treatment of mild depression but it is known to have a variety of effects on the central nervous system and can reduce the effectiveness of some widely used prescription medicines including oral contraceptives, anti-depressants, anti-convulsants and treatments for HIV infection.

Requirements to provide information

Perhaps the primary information that affects the public's confidence in the safety of a product is that it has undergone and passed a conformity assessment procedure, as signified by CE marking or a marketing authorisation number, although this is not permitted for certain sectors.[331] Some safety information poses little difficulty, such as date of manufacture, use-by date, batch number, identity of producer, product, ingredients/components, and quantitative data.[332] However, other aspects are more complex. Table shows that all of the product regulatory regimes require information to be included in labelling on wider safety issues, although the requirement is often expressed in very general language,[333] leaving individual producers to decide what information should be given on a product-specific basis, with the exception of medicinal products, for which the text of labelling and information must be approved in advance by the competent authority and must conform to the SmPC. The requirements for medicinal products and medical devices are greater and more detailed than for other types: for the former two types the categories of information are intended to be comprehensive whereas the theory underlying recognition of cosmetics, biocides and tobacco is that the safety properties of substances and ingredients used are known and not expected to alter significantly, and the conditions of use are generally known, so it is unnecessary to specify more extended categories of information. Inevitably, however, issues of consistency can arise.[334]

How much information?

There have long been requirements that information about products should not be false or misleading,[335] but difficult issues of judgment arise in the safety context[336] over how serious a risk

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331 There is, therefore, an argument for a Community mark to be authorised for all products, which would focus producers' minds on the need for pre-market verification of design/manufacture/labelling and risk assessment. However, this would only provide consumers with a level of confidence in the safety of products to the extent that such a level is achieved in practice.

332 Much of this information is intended to be of use to manufacturers and distributors in the event of a need to pass on post-marketing safety information to consumers or to recall products. For example, each centrally-authorised medicinal product has an unique identification number, which must appear on its packaging: Regulation (EEC) No 2309/93, article 12.1. The use of IT has significant implications: 'The IT revolution: The best thing since the bar-code: Smart labels may be about to change the way that companies distribute and sell almost everything they make', *The Economist*, February 8, 2003.

333 The rules for simple pressure vessels, lifts, recreational craft and arguably even the GPSD do not even require information to be provided on safe use. However, requirements often cover specific aspects of use, without including that general word. The approach to safety information requirements can, however, be seen as evolving and becoming more extensive and focussed over time, as appears from comparing the extent of the requirements with the dates of the various Directives.

334 There has been criticism of inconsistencies and deficiencies in the information and warnings given in patient leaflets for some medicines: A Herxheimer, 'Leaflets with NSAIDs do not warn users clearly – a UK survey', *The Pharmaceutical Journal* Vol 262, April 17, 1999, 559-561.

335 This is covered by Directives 84/450/EEC and 97/55 on false and misleading advertising, and national legislation on trade descriptions, and arises historically out of quality and adulteration concerns. There are specific controls on advertising of medicinal products (see ch 4), on the basis that this could affect public health were it to be excessive or ill-considered: Directive 2001/83/EC, recital 45. General controls on false

should be to justify being mentioned, how much information should be given and in what terms and with what level of detail, and so as to give proper information on individual risks and comparison between hazards.

Economic theory argues that providing complete information is irrational, and that optimal information should be given. This is where the marginal costs of supplying and processing the level and quality of information in question are approximately equal to the marginal benefits that are engendered.[337] It can be seen from Table 5 that although the legal requirement is that disclosure appears mandatory in principle, the quantity and substance of disclosure in most individual cases (medicines possibly apart) is in practice open to considerable discretion and judgment. In other words, for regulatory purposes, complete disclosure of all hazards and of the nature, incidence and severity of their risks and how to avoid them may not be required.

As stated above, the purpose of providing information is so as to enable consumers to make rational risk assessment decisions about whether and how to use a product, given the particular risks of hazards that it presents. The theory is, of course, vulnerable to personal differences, such as ability to rationalise simple or complex information,[338] literacy and linguistic barriers, variations in individuals' attitudes to risk, behavioural approaches and choices.[339] The achievement of communication of relevant information to the young and the elderly may be impossible, so warnings and instructions may be directed to non-users who may be able to control the use of a product. Viscusi considers that most product risks are readily perceived and the provision of information should pose little problem as a mechanism, but he highlights greater difficulty with more dimly understood health risks.[340] The principle that is established by product liability law is that there

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and misleading advertising are outside the scope of this work, but the ECJ has upheld national legislation under which a cosmetic cream could have been banned since its name contained the term "lifting", which it was objected would mislead consumers by giving the impression that there would be effects lasting for a certain period of time identical or comparable to surgical lifting, although the actual decision was left to the national court to make on the basis of social, cultural and linguistic factors, albeit with the comment that the average consumer, reasonably well informed and reasonably observant and circumspect, ought not at first sight to expect the description of such a cream to be misleading: Case C-220/98 *Estee Lauder* [2000] ECR I-117.

336 Aspects such as quality, price, and comparisons with other products also arise.

337 A Ogus, *Regulation: Legal Form and Economic Theory* (Oxford, 1994), 39 and ch 7.

338 Personal communications with a range of manufacturers indicate that product information is written for a notional Daily Mail reader with a reading age of 9 years of age.

339 For further consideration of risk perception and behavioural issues, see ch 19. A recent UK survey on medicinal products found that only around 30% of people read all the information in the leaflet, some 8-12% never read any of it, that some 40% felt that too little information was provided and 20% would like to see more information on the likelihood of the listed side-effects: National Audit Office, *Safety, quality, efficacy: regulating medicines in the UK* (The Stationery Office, 2003).

340 W K Viscusi, *Regulating Consumer Product Safety* (American Enterprise Institute for Public Policy Research, 1984), p 6.

should be complete transparency, in that the manufacturer should provide all relevant information that relates to the injury that occurred, excepting information that is common knowledge.[341]

Communication problems can arise over comprehension of large quantities of data or technical information.[342] There has long been a problem over how to provide of information on medicinal products that is intelligible to non-medical consumers without compromising scientific accuracy, particularly when extensive information on multiple risks is often required for individual products.[343] The issue arises for all products involving long-term use or systemic effects.[344] Behavioural research assists both content and presentation of information.[345]

These difficulties have been noted by the European institutions. In 1993 the Council requested the Commission to examine the need for and merits of a Community-wide solution to providing information on products by means of labelling and to study the possibility of establishing a Community framework for labelling requirements.[346] The Council specified the following issues, from which the emphasis on the consumer's viewpoint should be noted:

1. The Commission should consider that labelling would in particular have to be:

   - comprehensible, i.e. legible and easy for the consumer to understand;

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341 See for example Directive 85/374/EEC, article 6.1; C Hodges, *Product Liability: European Laws and Practice* (Sweet & Maxwell, 1993).

342 E Bardach and R A Kagan, *Going by the Book: The Problem of Regulatory Unreasonableness* (1982), 249-256. W A Magat and W K Viscusi, *Informational Approaches to Regulation* (1992), 102. Opinion of the Economic and Social Committee on 'General Product Safety', 2000/C 51/16, OJ No C 51/67, 23.2.2000, para 3.3.1.2 expressed concern over information 'overload'.

343 J Collier, 'Patient-information leaflets and prescriber competence', *The Lancet*, Vol 352, November 28, 1998 concludes that the amount of information in each patient leaflet is extensive and in some cases likely to be very detailed. An interesting initiative is 'The Informed Patient' research project at the University of Cambridge on how to provide appropriate information to patients and consumers (2003). Improving the quality of patient information on medicines is a key task of the Community, which is concentrating on production of comprehensible patient information leaflets, for which there will be mandatory readability tests: Communication from the Commission *A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action* COM(2003) 383, 1.7.2003.

344 The Communication from the Commission on Community and National Measures in relation to Breast Implants, COM(2001) 666, 15.11.2001, said "Women who are considering receiving breast implants should receive all relevant and up to date information allowing them to make a well-informed and considered decision, in full knowledge of the potential risks and benefits of the intervention and the breast implants. Women should be aware that breast implants are a long-term commitment." (Annex 2).

345 J Croft and F Harris, *Writing Safety Instructions for Consumer Products* (Department of Trade and Industry, 1998) refers to different delivery channels, such as levels of packaging, leaflets, markings on products, pictograms, symbols, colours, highlighting of information, boxes, typeface, specific language forms or words. It has been said: "Pictures on labels and in advertisements can also exert powerful influences on a prospective purchaser and, in some product sectors, may have a greater significance than names and other descriptive materials." *FAC Review of the use of terms Fresh, Pure, Natural etc in Food Labelling 2001* (Food Standards Agency, 2001). Use of symbols in preference to wording is a requirement for medical devices: Directive 93/42/EEC, Annex I section 13.1. A symbol for durability of cosmetic products greater than 30 months is mandated from 11 March 2005: Directive 2003/15/EC.

346 Council Resolution of April 5, 1993 on future action on the labelling of products in the interest of the consumer, 93/C 110/01, OJ No C 110/1, 20.4.93.

- distinctive, i.e. make the necessary distinction between product labelling, on the one hand, and other information and advertising given on the product, on the other;

- relevant, i.e. not be misleading and contain sufficient information enabling consumers to make purchase decisions based on the information they find important regarding a particular product;

- transparent, i.e. enabling the consumer to compare different products within the same group of products in relation to quality and price;

- verifiable, i.e. subject to appropriate supervision according to national legislation or practices, in order to ensure that the labelling complies with the agreed requirements;

- practicable, i.e. easy for manufacturers, retailers and control services to implement....

The result of the above initiative was that the Council proposed "Indications for Good Operating Instructions for Technical Consumer Goods" which are useful but very generalised and therefore limited:

> "Whereas, in the light of the growing variety of items available on the market and the frequent innovations triggered by technical progress, operating instructions for technical consumer goods are often perceived by consumers as inadequate, both because they are unclear and present language difficulties, owing to faulty translations or to the use of terms which are too complex, and because they lack structure and have inadequate content; whereas the use of the appropriate language is crucial for clear, user-friendly operating instructions".[347]

These difficulties have also been noted by the Economic and Social Committee, which was unable to suggest a solution other than the development of practical guidelines and major further investigation:[348]

> "3.3.1.1. The Committee is concerned that information on labels and instructions, whether in the form of words, diagrams or pictograms, is not always clear, easy to understand, remember and apply.
>
> 3.3.1.2 Sometimes there is even an excess of information, which can be overlong and repetitive, with manufacturers and distributors giving extremely detailed safety instructions and identifying of every foreseeable use and misuse. The result is that consumers either avoid reading the material or experience mental 'overload' and fail to understand essentials.
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> 3.3.1.3 The Committee, therefore, suggests there is a need for practical guidelines appended to the GPSD to clarify the ways in which information should be presented.

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347 Council Resolution of 17 December 1998 on operating instructions for technical consumer goods, 98/C 411/01, OJ C 411/1, 31.12.98, recital 5.

348 Opinion of the Economic and Social Committee on "General Product Safety", 2000/C 51/16, OJ C 51/67, 23.2.2000: see also Opinion of the Economic and Social Committee on the "Proposal for a directive of the European Parliament and of the Council on General Product Safety", 2000/C 367/11, OJ No C 367/34, 20.12.2000, para 3.4.1.

3.3.1.4 A major collaborative and co-ordinated investigation is also required, the object of which is to examine and monitor the adequacy of safety communication, including electronic communication and E-commerce."

Some guidelines have been developed on a horizontal[349] or vertical[350] basis but the former are from one Member State and the latter cover limited vertical sectors. The Council has produced generalised guidelines and called for more work on this issue, particularly through standards.[351]

Language of labelling

The issue of language raises interesting issues. There are two, opposed, starting principles. First, national linguistic requirements constitute a barrier to trade. However, secondly, the public safety point is that users must be able to understand the information provided for them and, as Europe consists of multiple nationalities with several languages and no common language, information can therefore only be provided so as to satisfy the intelligibility requirement if it is provided in the local language of users.[352] In discussing the Community's need itself to communicate more actively with the general public so as to strengthen democracy and improve confidence in the Community, the Commission has said:

"Information should be presented in a way adapted to local needs and concerns, and be available in all official languages if the Union is not to exclude a vast proportion of its population[,] a challenge which will become more acute in the context of enlargement."[353]

This policy is widely accepted by legislators[354] and regulators, as evidenced by the Economic and Social Committee:

"The Committee also draws attention to the particular importance of clear, durable warnings and cautions, especially when the language used is not that of the country of the consumer, or when the translation into the native language is poor, and suggests the following:

- warnings should be given in the main language(s) of the country in which the product is sold;
- a lack of prescribed warnings and labels should be specified as reasons for prohibiting the import of a product from third countries;

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349 *Instructions for consumer products: Guidelines for better instructions and safety information for consumer products*, Department of Trade and Industry, 1988: these cover safety/warnings, writing, layout, illustrations, tables and typography; *Writing Safety Instructions for Consumer Products*, Department of Trade and Industry, 1998.

350 *A Guideline on the readability of the label and package leaflet of medicinal products for human use*, European Commission, 1998. *Food Labelling Action Plan: Clear Labelling Task Force draft recommendations on Ideal Label Formats*, Food Standards Agency, LSA 13/206/4/161, 8 August 2001.

351 *Council Resolution of 17 December 1998, supra.*

352 Case C-169/99, *Hans Schwarzkopf GmbH & Co KG v Zentrale zur Bekaempfung unlauteren Wettbewerbs eV* [2001] ECR I-5901.

353 *European Governance: A White Paper*, COM (2001) 428, 25.7.2001.

354 See Council Resolution of 17 December 1998 on operating instructions for technical consumer goods, 98/C 411/01, OJ C 411/1, 31.12.98.

- in special cases essential product safety information should be available wherever possible in alternative forms, such as braille, for the benefit of visually-handicapped people."[355]

The Court of Justice has held that article [28] of the Treaty and article 14 of Directive 79/112 on labelling of foodstuffs preclude a national rule from requiring the use of a specific language for labelling of foodstuffs without allowing for the possibility for another language easily understood by purchasers to be used or for the purchaser to be informed by other means.[356] This decision resulted in Directive 2000/13/EC, article 16 prohibiting the sale of foodstuffs for which the specified particulars do not appear in a language easily understood by the consumer, and permitting a member state in which a product is marketed to stipulate that the particulars shall be given in one or more of the official Community languages which it shall determine.

Some vertical product Directives require that labelling be provided in local languages[357] but others leave the decision to Member States[358] or are silent on the issue.[359] Translation requirements raise objections from manufacturers on grounds of the cost of multiple translations[360] but also a possible diminution in safety as a result of information overload through the provision of very long leaflets and the lack of space on a product or its packaging to provide all mandatory information in all languages: these aspects deserve further study. It is, of course, intended that products will circulate within the internal market, both on a first- and second-hand basis, and the language of information may be a problem here where the manufacturer's original information is not in a language of a state where the

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355 Opinion of the Economic and Social Committee on 'General Product Safety', 2000/C 51/16, OJ C51/67, 23.2.2000.

356 Case C-366/98 *Re Criminal Proceedings against Geffroy and Casino France SNC* [2000] ECR I-6579.

357 Medicinal products (Directive 92/27/EC, articles 4.2 and 8); tobacco (Directive 2001/37/EC, article 5.1); biocides (Directive 98/8/EC, article 20.6); PPE (Directive 89/686/EEC, Annex II, para 1.4).

358 Member States have optional powers to require that labelling be in their national language(s) for cosmetics (Directive 76/768/EEC, article 7.2), medical devices (Directive 93/42/EEC, article 4.4 and virtually all Member States require this), and toys (Directive 88/378/EEC, article 11.5). For tobacco, the labelling must be only in the official language(s) of the Member States where the product is placed on the market, so producers subsequently exported to other Member States are not subject to relabelling (Directive 2001/37/EC, article 5.6(e)). For machinery (Directive 98/37/EC, Annex I. Para 1.7.4(b)) the instructions must be in one of the Community languages but there must also be a translation into the language of the country in which the machine is put into service, save for maintenance instructions, where this is undertaken by the manufacturer's spacialised personnel.

359 EMC, LVD and GPS, although it is arguable that an obligation to provide information to enable a product to be used safely is not satisfied when crucial information is not intelligible to users generally.

360 Considerations of cost being irrelevant to safety.

product ends up,[361] or where the original labelling has been lost or obscured or is not in the local language.[362]

Labelling of cosmetics must identify ingredients through a common name as specified in a Common Ingredients Nomenclature (in which names are sometimes in Latin), although Member States may require use of a language easily understood by the consumer.[363] This approach therefore aims at uniformity across Europe but permits national variations, thereby increasing cost. It can be argued that consumers do not normally need to be able to identify all ingredients before purchase since, if they subsequently develop allergies to particular ingredients, the information, first, needs to be available to toxicologists, who will undertake patch testing to identify the sensitising ingredient and who will be familiar with all names used and can inform individuals to beware of the possible names for specific ingredients. On the other hand, anyone who has an allergy to an identified substance will need to know its name, in whatever language, and there is the issue of consumers being unaware of new variations or combinations.

Remote labelling

A related issue which is developing is whether information may be provided through a manufacturer's website or email rather than on paper provided with a product. This would entail the safety advantages of speed of updating, and no restriction on volume of information providable.[364] This method depends on there being virtually total certainty that all users will have web access either before purchase in a retailer or at home. The latter may be some years away for consumer products generally but may be already achieved for products provided to professionals, such as in-vitro diagnostic medical devices. A pilot study covers an internet platform for product warnings in the electrical field plus recreational craft.[365]

The availability of information on the internet in relation to medicinal products has both advantages and disadvantages. It empowers consumers but can be diffuse, difficult to locate, requires control

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361 Medical device and in-vitro diagnostic device manufacturers have contemplated not to provide products for smaller national markets because of the cost of translation: *The Language of Labelling for Medical Devices* (EUCOMED, 1994).

362 The distributor of a consumer product would have a duty to pass on or provide appropriate information when supplying a product (Directive 2001/95/EC, article 5.2) and in default of which may be classed as a producer and subject to the article 5.1 duty (ibid, article 2(d) (iii)).

363 Directive 76/768/EEC, articles 5a and 7(2). Under Directive 93/35/EEC and Commission Decision 96/335/EC the Commission has adopted a common ingredients nomenclature (INCI), in which some names are in Latin.

364 *Position Paper on Electronic Labelling* (EUCOMED, 2 June 2003).

365 Senior Officials Group on Standardisation and Conformity Assessment Policy, minutes of meeting, 26 November 2002.

over content and at worst can provide opportunities for mis-information and unscrupulous selling of inappropriate or even counterfeit products.[366]

Promotion

The way in which a product is promoted may affect its safe use. For example:

> "Advertising [of medicinal products] to the general public, even of non-prescription medicinal products, could affect public health were it to be excessive and ill-considered; ...[and] ought therefore to satisfy certain essential criteria which ought to be defined."[367]

Vertical regulation of promotion in relation to safety aspects[368] is, however, only in place for medicinal products for human use[369] and in prospect for tobacco, where the concern relates primarily to prevention of promotion to children.[370] Every advertisement for a biocidal product must state "Use biocides safely. Always read the label and product information before use."[371]

Horizontal measures prohibit misleading advertising and regulate comparative advertising.[372] Misleading advertising is defined as "any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor".[373] Comparative advertising between products is permitted when certain conditions are met, including that goods or services are not presented as imitations or replicas of goods or services which bear a protected trade mark or trade name.[374]

Conclusions on labelling

It has been seen that every product sector requires that some labelling information be provided with a product. Some vertical measures, for what might be considered to be the more safety-sensitive products, specify the categories of information that need to be provided, and a general horizontal obligation to provide information exists for consumer products. Difficulties exist about how much information should be provided on instructions for use and warnings, and how it should be provided

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366 S McKechnie, "Health on the internet: a mixed blessing", *Consumer Policy Review*, May/June 1999, Vol 9, No 3, 86.

367 Directive 92/28/EEC, recital 4.

368 Various measures relate to other trading aspects such as prices and commercial terms.

369 Directive 2001/83/EC, Title VIII, replacing 92/28/EEC on the advertising of medicinal products for human use. National systems of control differ, for example between prescription-only products and over-the-counter products.

370 Directive 98/43/EC on tobacco advertising was ruled unlawful by the Court of Justice in Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8419.

371 Directive 98/8/EEC, article 22.

372 Directives 84/450/EEC and 97/55/EC.

373 Directive 84/450/EEC, article 2.2.

374 Directive 84/450/EEC, article 3a.

in order to optimise safety. The legal requirements are almost totally silent on this issue. Certain sectoral initiatives on best practice have occurred but there seems to be a need for more research to be undertaken on these issues in order to generate horizontal guidelines that inter-relate appropriately with vertical guidelines where the latter are needed.

11. PRODUCERS' POST-MARKETING OBLIGATIONS

The purpose of producers' post-marketing obligations

It is suggested that the essential purpose of such a system is to *enable the producer to be informed of the risks which appear from use of the products, to evaluate them, and to take appropriate action* in relation to safety of products already placed on the market or yet to be produced. Indeed, these are all aspects which are included in the Quality Systems Standard, ISO 9000, although the scope of legal provisions addressing safety and of quality system provisions are not fully the same: a quality system would certainly be expected to include document retention policies, arrangements for checking the quality of ingredients and components as well as the finished product, process control records, as well as systems for monitoring quality generally and auditing the system as a whole from time to time. However, an essential feature is constant re-appraisal: the constant evaluation of existing data and conclusions on safety and risk in the light of new data or perspectives.

The different legal requirements

Both the vertical medicinal product and medical device systems and the horizontal GPS obligations essentially require a producer to operate a post-marketing product safety vigilance system. However, the nature, extent and legal obligations of each of these systems differ significantly. It is also implicit that the nature and extent of the system required by the GPSD will vary from producer to producer, depending on the nature of their activities and on the characteristics of the product involved, and the legal provisions are without guidance on such matters. The other sectors are essentially silent on post-marketing obligations on producers.

The GPSD provisions

It is instructive to consider the GPS provisions first, since these were specifically intended to set out "rather simple general principles".[375] As justification for imposing post-marketing obligations, the 2001 GPSD noted that reliance solely on observance of a pre-marketing safety obligation is, as a general proposition, inadequate:

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375 Proposal for a Directive, Explanatory Memorandum, European Commission, 1989. Although the pharmacovigilance system, and to a lesser extent the medical devices vigilance system, contain what are currently viewed as comprehensive provisions, the obligations that these contain are not set out in the form of a set of general principles for post-marketing safety in the way that the GPSD provisions are set out, but rather contain specific individual obligations.

"It is appropriate to supplement the duty to observe the general safety requirement[376] by other obligations on economic operators because action by such operators is necessary to prevent risks to consumers under certain circumstances."[377]

The GPSD duties relate only to consumer products[378] and there are no equivalent horizontal provisions for non-consumer products; this begs the questions of whether there should be post-marketing controls for non-consumer products and what they should be. That point is related to the difficult issue of the overlap between the horizontal GPSD provisions and vertical sector-specific provisions,[379] and how this might best be resolved. The general position is shown in Table .

The GPSD includes obligations of producers[380] and distributors.[381] The GPSD obligations on producers, as extended by the 2001 Directive, are-

1. To place only safe products on the market[382]: this is a pre-marketing duty, discussed at chapter 8.

2. To provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks *(duty 2)*.[383] This duty clearly applies pre-marketing but whether it applies post-marketing is not entirely clear and depends on whether the words "throughout the normal or reasonably foreseeable period of its use" qualify "to provide consumers with the relevant information" or "the risks". The former is correct as a matter of language but the point is largely academic in view of the existence of a post-marketing obligation to inform consumers, as arises below.

3. Within the limits of their respective activities, to adopt measures commensurate with the characteristics of the products which they supply, enabling them to:

   (a) be informed of risks which these products might pose (*duty 3*);

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376 Note: This is the obligation to place only safe products on the market contained in Article 3.1 of Directive 2001/95/EC.

377 Directive 2001/95/EC, recital 17.

378 A product covered by the GPSD is defined in Article 2(a).

379 The general theory is that each of the GPSD post-marketing obligations apply to all consumer products unless a particular GPS obligation is already covered (ousted) by a sectoral-specific obligation at Community level: see Directive 2001/95/EC, article 1, recitals 11-14; see also Directive 92/59/EEC, article 1. Whilst the theory may be simple, in practice enormous confusion has existed in practice on this point: *Revision of Directive 92/59/EEC on General Product Safety: UNICE comments,* UNICE, 27 September 2000. This borderline issue is outside the scope of this thesis.

380 Defined at Article 2(e)

381 Defined at Article 2(f): see ch 13.

382 Directive 2001/95/EC, article 3.1.

383 Directive 2001/95/EC, article 5.1.

(b) choose to take appropriate action including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recalls from consumers (*duty 4*).[384]

The following specific measures are stated as examples to be included in the measures referred to in (a)[385]:

(i) an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified (*duty 5*) and

(ii) in all cases where appropriate,

(a) the carrying out of sample testing of marketed products (*duty 6*),

(b) investigating complaints (*duty 7*)

(c) if necessary, keeping a register of complaints (*duty 8*) and

(d) keeping distributors informed of such monitoring. (*duty 9*).

It is also specified that action such as that referred to at (ii) above shall be undertaken on a voluntary basis or at the request of the competent authorities for any dangerous product already on the market (*duty 10*).[386] Duty 5 is a pre-marketing obligation but duties 3, 4, 6-8 all apply post-marketing and will be referred to further below.

4. Immediately informing the competent authorities where producers know or ought to know, on the basis of the information in their possession and as professionals, that a product they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement (*duty 11*).[387]

5. Within the limits of their respective activities, cooperate with the competent authorities, at the request of the latter, on action taken to avoid the risks posed by products which they supply or have supplied (*duty 12*).[388]

In order to facilitate the following discussion, a number has been allocated to each of the above duties: it will be seen that the way in which each is expressed is often as generalised principle rather than as a requirement for specific action, and several duties are interlinked or even overlapping. A significant number of issues arise over the scope and precise interpretation of these provisions, which are discussed elsewhere, principally in chapter 11.

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384 Directive 2001/95/EC, article 5.1, third para.
385 Directive 2001/95/EC, article 5.1, fourth para.
386 Directive 2001/95/EC, article 5.1, fifth para.
387 Directive 2001/95/EC, article 5.3.
388 Directive 2001/95/EC, article 5.4.

Radio and telecommunications terminal equipment

Although detailed provisions of some New Approach Directives are discussed below, a general comparison of the respective approaches of the GPSD and of the New Approach is instructive. Directive 1999/5/EC on radio equipment and telecommunications terminal equipment (R&TTE) provides that a manufacturer may choose one of three conformity assessment procedures for certain types of equipment (not all). Only one of the several available conformity assessment procedures (namely, full quality assurance - Annex V) includes a requirement that a notified body continues to inspect the manufacturer's quality system documentation, which must be kept updated. The documentation comprises details of design control, manufacturing control, inspection and testing, and storage, plus "the means to monitor the achievement of the required design and product quality and the effective operation of the quality system". It is by no means clear that these provisions include a requirement for the collection of post-marketing safety data or its evaluation, or the taking of appropriate action.

Theoretical criteria for evaluation of post-marketing obligations

What steps should be included in a comprehensive system of regulation of producers' post-marketing activities? It is suggested that a comprehensive[389] theoretical approach to producers' obligations would involve operating a systematic procedure comprising the following actions, probably in the following sequence:

(a) assembling technical documentation on the product's design and manufacture and labelling, including a risk assessment, and keeping it updated and available;

(b) collecting, recording and collating safety information from users, retailers, distributors, regulators or any other source, including scientific and technical literature, on how safe the product is when used in practice and whether it continues to conform to the standards of safety as these evolve in the light of new scientific and technical information;

(c) if appropriate, the investigation of such information;

(d) the assessment of that information, perhaps with external technical, regulatory, medical or legal advice, and updating the product's risk assessment;

(e) reporting information to a regulatory authority;

(f) making a decision on whether any changes need to be made or action taken as a result of that reassessment, such as (i) changes in the design, manufacture, labelling or packaging in relation to products not yet placed on the market, or (ii) action such as informing users, distributors,

389 It must be stressed that this is not necessarily appropriate or proportionate for each product.

regulators or others of changes in potential risks with the product, or instituting a recall of products already placed on the market;

(g) implementing the decision(s) taken by taking appropriate action.

These steps will now be considered in greater detail and will provide a framework for evaluation of the extent to which obligations on producers that would contribute to product safety are included in the various legislative systems: the overall position is summarised in Table 7.

(a) Keeping technical documentation

The essential purpose of regulating this activity mirrors the rationale for keeping pre-marketing documentation. First, it is to ensure that there is a record of the basis on which the product was considered to be sufficiently safe to be placed on the market at the time it was marketed. Secondly, it may also be necessary to keep the original information up-to-date (discussed in section (b) below). The existence of an obligation to keep data has various functions: it encourages manufacturers to undertake an evaluation and approval process; it provides a record that can be audited; and, of particular importance in the present context, it provides information that can be re-evaluated in the light of subsequent information.

The issues that arise here, therefore, in evaluating the existing legislation are:

- does the legislation specify an obligation to keep the documentation on which the approval of the product's marketing was based?
- is the documentation that should be kept specified?
- who keps the information and where is it to be kept?
- is there an obligation to keep it up-to-date? This is considered under section (b) below.
- for how long should particular documentation be kept?
- should access to such documentation be transparent: to what extent should authorities, and the public, be entitled to have access to what documentation? This is a question with wider implications than just for post-marketing, and is discussed further in chapters 10 and 12, in relation to the public and the authorities, respectively.

What information must be kept?

Nearly all vertical regulatory Directives require a manufacturer to assemble and keep technical documentation which controls a product, encompassing its design, production, labelling, packaging,

all in the form and status in which its marketing was approved. A general description of the categories of information that are required is usually specified.[390]

In contrast, there is *no* such explicit obligation for consumer products covered solely by the GPSD, which merely have to satisfy the general safety requirement, and have appropriate labelling and marking (duties 1, 2 and 5). Yet, as a practical matter in every case save for the simplest products, a manufacturer could only assure compliance with these two pre-marketing obligations and also with the GPSD post-marketing obligations if he had assembled satisfactory technical documentation, including a risk assessment. It is difficult to see how a producer could logically conclude that the level of risk with a product is satisfactory at one point in time and later conclude, on the basis of further information, whether the possibly increased level of risk is or is not legally acceptable, without having relevant technical documentation and an up-to-date risk assessment.

Who keeps the information and where?

Some systems require that the controlled post-marketing information must be available to the authorities, if they wish to inspect it, in one place.

For medicines, the particulars and documents that accompany the marketing application are lodged with the competent authority to which they are sent. The requirements on a marketing authorisation holder to keep the documentation are summarised in Table 8, and it is implicit in that the holder is required to notify the authority of any change in the particulars and documents submitted in support of the grant, or to apply for authorisation if he proposes to make any alterations in them.[391] In relation to new ADRs, the requirement is that "information about all suspected adverse reactions which are reported to the personnel of the company, and to medical representatives, is collected and collated in order to be accessible at least at one point within the Community".[392]

Similarly, it is implicit that the applicant for an authorisation for a biocide will keep a copy of his submitted dossier, which can be reviewed at any time,[393] and amended or cancelled in the light of developments in scientific and technical documentation.[394]

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390 See Directive 2001/83/EC, article 8.3 and Annex I for medicines; Annex I of New Approach Directives; Directive 76/768/EEC, article 7a for cosmetics; Directive 98/8/EC, article 8 for biocides.

391 see Regulation (EEC) No 2309/93, article 15.

392 Directive 2001/83/EC, article 103 (a); Regulation (EEC) No 2309/93, article 21.

393 Directive 98/8/EC, article 6.

394 Directive 98/8/EC, article 7.

For cosmetics, the controlled pre- and post-marketing information is to be kept "readily accessible" at the address specified on the label as being that of the manufacturer or the person responsible for marketing the product who is established within the Community.[395] This information constitutes what is known as the Product Information File, which is a notional rather than physical concept: the information must be accessible and identifiable but individual items need not be kept physically together in a dossier, although they must all be kept at the manufacturer's address.

Many New Approach Directives are silent on the issue of document retention,[396] although this is implicit at least where quality assurance systems based on harmonised standards are operated, and the Commission's guidelines state that the technical documentation must be kept for at least 10 years from the last date of manufacture of the product.[397] The obligations are generally directed only at one person, the product's manufacturer,[398] so any ongoing obligations could only be directed at him.

Particular obligations should be noted for medical devices. The most commonly used conformity assessment procedure provides that the manufacturer's application to the notified body for assessment of the quality system must include an undertaking by the manufacturer to keep the approved quality system adequate and efficacious.[399] This implies that the documentation which forms part of the quality system from time to time will be kept, but does not require that superseded documents are kept. By a separate provision[400], however, the manufacturer of a medical device must, for a period ending at least five years after the last product has been manufactured, keep at the disposal of the national authorities:

- the declaration of conformity,
- the documentation on the quality system,
- any substantial changes to the quality system or product-range,
- the documentation describing the design, manufacture and performances of the product,

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395 Directive 76/768/EEC, article 7a.1.

396 Exceptions are noted at Table 8. Directive 98/37/EC on machinery Annex V is unusual in requiring that specific documentation be kept available for inspection. There are no explicit provisions for, for example, toys, low voltage or EMC products, non-automatic weighing instruments, construction products, or appliances burning gaseous fuels.

397 *Guide to the implementation of directives based on the New Approach and the Global Approach* (European Commission, 2000).

398 The term "manufacturer" can be defoned in Directives to cover a wider group than physical manufacturers, and include importers into the Community and own-branders.

399 Directive 93/42/EEC, Annex II, para 3.1.

400 Directive 93/42/EEC, Annex II, para 6.1; similar five year provisions apply under other conformity assessment annexes.

- the decisions and reports from the notified body on any quality system audit, design examination certification, change, or surveillance inspection or assessment.

The manufacturer must in practice draw up a technical file, which comprises the technical documentation required to demonstrate the conformity of the product with the essential requirements, or to indicate the essential requirements that are covered by any harmonised standards that have been applied[401], and that the standard has been satisfied. A technical file is a notional rather than physical concept, since parts of the controlled documentation may be physically kept at differing locations and companies around the world. This decentralisation is accepted as being the only practical way of working in circumstances where particular items of technical information that are produced by different entities. The documentation should be subject to constant updating. It may also form part of the notional technical files of more than one product type, although in practice manufacturers are expected to be able to produce any relevant information swiftly to the authorities. A notional or virtual technical file may, therefore, be held for individual products, which contains a control sheet that identifies and controls each supporting document, its date, revision number and location.

How long should the information be kept?

Table 8 shows the time periods specified for keeping the controlled pre-marketing information: and records the differences between the sectors.

(b) Collecting new information on safety

The objective

The purpose here is to ensure that new safety information is captured, so that there is a complete and up-to-date body of safety information that adds to the pre-marketing predictions and assessments, by providing information from actual use, and on which an ongoing reliable reassessment of safety can be made.

The practical issues that arise include:

- What information should a producer record, how, and for how long? For example, should he record only verified information, only complaints, or any potential safety or quality related issue?

- Is there an obligation to keep the pre-marketing controlled documentation up-to-date, for example in the light of advances in scientific and technical progress?

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401 *Guide*, supra, 5.3.

Two approaches

No regulatory system has this obligation in precisely these terms. Broadly, two different approaches are adopted. One approach, taken by the GPSD, is to specify that the producer must adopt a system that delivers the *result* that he is informed of the risks that his products present, the mechanism by which this conclusion is reached being up to him given the particular type of product and circumstances. The other approach, exemplified by medicines and medical devices, is that the manufacturer must collect *a specified type of information*, namely reports of adverse incidents associated with a product.

Medicinal products

The Pharmacovigilance system comprises some legal obligations and extensive guidance: the overview is described at Appendix 1. The primary legal obligation on the marketing authorisation holder is required to record all suspected adverse reactions[402] that have been brought to his attention by a healthcare professional.[403] Guidelines specify that the marketing authorisation holder is expected to screen the worldwide scientific literature for case reports of suspected adverse reactions.[404] An authorisation holder must forthwith inform the authorities of any new information which might entail the amendment of the particulars and documents that were lodged with the application for marketing approval or the summary of product characteristics, labelling or package insert.[405] He must also take account of scientific and technical progress relating to methods of manufacture and control, and introduce any changes that may be required so that the medicinal product will be manufactured and controlled by means of generally accepted scientific methods.[406]

Medical devices

The Medical Device Vigilance system comprises a mixture of law and guidelines, but in neither case is as extensive as the Pharmacovigilance System. Instead of a specific requirement to record data,

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402 An adverse reaction is defined as a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function: Directive 2001/83/EC, article 1.11.

403 Regulation (EEC) No 2309/93, article 22.2; Directive 2001/83/EC, article 104.1. See chapter 4 for possible extension of reporting to patients.

404 Pharmacovigilance Guidelines, European Medicines Evaluation Agency, Part I, Medicinal products for Human Use, 1.Notice to Marketing Authorisation Holders, section 1.2.2.

405 Regulation (EEC) No 2309/93, article 15.2; there seems to be no equivalent provision for medicinal products that are subject to national approvals save for the last sentence of Directive 2001/83/EC, article 8 but it is unclear whether that obligation to update the information on a regular basis applies only to the immediately proceeding sub-paragraph (l) or to all the information specified in article 8.

406 Directive 2001/83/EC, article 23; Regulation (EEC) No 2309/93, article 15.1.

there is a general legal requirement that the manufacturer "institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action."[407] This is followed by an obligation to report specified types of information to the competent authorities, which implies that information at least within those categories must be recorded. It is an essential requirement that devices "conform to safety principles, taking account of the generally acknowledged state of the art."[408]

Biocides

There is merely an implicit obligation on the authorisation holder to have a system to collect and evaluate new information, which arises from the explicit obligation to notify specific new information to the authorities, discussed below. The extent of the vigilance system is, therefore, unspecified, save as to its result.

Cosmetics

The manufacturer or other specified person must keep available "existing data on undesirable effects on human health resulting from use of the cosmetic product."[409] No further details are specified. In practice, information is likely to come from scientific sources and from consumer complaints.

The GPS approach

GPS duty 3 requires that a producer

> "adopt measures commensurate with the characteristics of the products which they supply, to enable them to be informed of risks which these products might present...."[410]

This wording raises issues of the scope of the system that is required and the result that is required. It is convenient to take these issues in reverse order. The system must be such that the producer must *be enabled to be informed* of the risks that products *might* present: he must therefore have a system that is of sufficient capacity.

The second question is how extensive the system should be. Should it be purely reactive or pro-

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407 Directive 93/42/EEC, Annex II, para 3.1, 7th indent, but there is controversy over whether this has appropriate legal force, being enforceable for all devices except Class I ostensibly only as breach of an undertaking given to a notified body, and for Class I devices seemingly being unenforceable, subject to any specific provisions of national laws.

408 Directive 93/42/EEC, Annex I, para 2.

409 Directive 76/768/EEC, article 7a.1(f).

410 Directive 2001/95/EC, article 5.1.

active? In other words, should it be limited to receiving any reports which are passed on by distributors or users? Should it be limited to reports for which there is sufficient information so that it can be seen that the report falls within a certain definition of an adverse event, thereby excluding information such as unverified preliminary complaints? Or should a producer be required positively to seek market information, to follow up complaints, to test returned products, or actively to review scientific and technical literature?

The answer to these questions is not clear from the legislation, but some factors which should be relevant in answering these questions would include the following. First, the scope of the system is to some extent defined by the definition of the result which it is a requirement to achieve (discussed above). Thus, whatever the scope of the system, it must be sufficient to achieve the required result, namely have the capacity to inform the producer of the risks which his products might present. Secondly, the scope is subject to considerations of appropriateness and proportionality, since the measures must be "commensurate with the characteristics of the products". This implies that different product types will require systems of differing scope. The onus seems to be on a producer to demonstrate that it is not appropriate for him to adopt all or some of the contemplated measures in relation to his particular products. An own brander or representative or supplier who is classed as a producer may be able to establish this where he is able to rely on the fact that his manufacturer or supplier adopts appropriate measures or operates systems which adequately cover these safety measures (i.e. marking, sample testing, investigating complaints and informing distributors).

Thirdly, whatever the scope of the obligation should be in theory, it is in practice restricted on a subjective basis, by the wording "within the limits of their respective activities". This wording limits the extent of the obligation from producer to producer, or distributor to distributor, on a subjective basis: the UK Department of Trade and Industry considers that the wording refers to the capacity of a person, given his position in the supply chain, to influence the safety of a product.[411]. This is seemingly limited by the actual activities of the particular operator, not what his activities ought reasonably to be, and by the extent of his resources. Nevertheless, the cost of full compliance with this requirement may well be high for many manufacturers and particularly suppliers, especially those turning over a large volume of products. Whilst the cost of compliance with a safety requirement might not normally be relevant to the question of whether the requirement has been complied with, cost is a factor which may affect the decision of producers in practice: it would be unrealistic to ignore

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411 *The General Product Safety Regulations 1994: Guidance for Business, Consumers and Enforcement Authorities*, Department of Trade and Industry 1994, para 32.

it and it might be argued that it is relevant in law, particularly in circumstances where the anticipated risk is low but the cost of taking a measure would be high. This is merely to adopt the risk/benefit test which is used in other circumstances, such as in licensing decisions on medicinal products and in product liability theory.

The GPSD contains some inconsistency between the approach to safety and information required pre-marketing and post-marketing. On the one hand, it recognises that a product may be treated as safe and may be placed on the market where its risks are of an acceptable minimum compatible with its use under normal or reasonably foreseeable conditions of use[412]. Information should be provided to consumers on the risks inherent throughout the normal or reasonably foreseeable period of use, where such risks are not immediately obvious without adequate warnings[413]. But, on the other hand, the producer has to be enabled to be informed of risks which the product might present[414] and this apparently means all risks, even those not arising under normal or reasonably foreseeable conditions. That might involve extensive, costly and disproportionate measures, even assuming that such total knowledge is achievable. Furthermore, such total knowledge would be pointless when the obligation to inform consumers is less extensive.

The GPSD notes four specific but somewhat different examples of measures to enable producers to be informed of risks, which are expressed to apply "whenever appropriate", namely:

- marking of the products or product batches in such a way that the product and its producer can be identified,[415]
- sample testing of marketed products,
- investigating complaints
- and
- keeping distributors informed of such monitoring.

A major complaint with the generalised formulation of the GPS duties is that the above practical questions on the scope of what will be a compliant system for a particular product are not answered. The answer seems to be "it depends" and to vary for different product sectors. There is potentially

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412 Directive 2001/95/EC, article 2(b).
413 Directive 2001/95/EC, article 5.1.
414 Directive 2001/95/EC, article 5.1.
415 Product or batch marking can facilitate effective product recall but also make it more efficient and cheaper by restricting the recall to specific identifiable production and avoiding recalling items unnecessarily.

great variation between different sectors and no guidance, even in non-legal form, on what would constitute compliance.

(c) Investigation

The purpose of requiring producers to investigate new information is that certain post-marketing information that they receive may be unreliable, perhaps because it is incomplete or inaccurate, and it is known to be important that it be investigated and verified before being relied on, so that a properly reliable updated assessment of safety can be made. This is a requirement to be pro-active rather than, as with mere receipt of information, passive.

The primary example of where this arises is that of medicinal products, where it is essential that adverse reaction reports associated with medicinal products be investigated in order to verify the facts and assess causation. Investigation is not mentioned in relation to cosmetics, biocides or any New Approach measures other than medical devices. There is no reason why issues of the accuracy, reliability and conclusiveness of reports for such products should not arise, and therefore why investigation should not be relevant.

Indeed, investigating complaints is one of the specific examples of measures referred to as being appropriate in the GPSD, and therefore may apply to consumer products that come under the new approach. But no further guidance is given on whether a producer should investigate every report of a potential adverse event (as is a requirement for medicines) or some or none. There is a clear argument for criteria to be developed which would assist in assessing what should be investigated and to what level of investigation for specific products, covering such issues as whether an expert should be involved and, if so, with what qualifications.

(d) Assessment

This is, of course, the intellectual crux of this series of activities, although if positive action needs to be taken then that is the most important focus. As discussed above under section (b), the purpose of collecting, recording and checking the information is that it be assessed. This activity is implicit for all product types. But how much information should be considered? To what extent is it important who should consider the information: experts with particular qualification, a multi-disciplinary committee, persons independent of the company?

Medicinal products

The essence of the pharmacovigilance system is evaluation of new ADR information, but there is no explicit regulatory obligation that this be done. A marketing authorisation holder must involve a qualified person who has personal and professional responsibilities for establishing and maintaining the pharmacovigilance system.[416] In practice, the qualified person works with the company's medical staff and sometimes outside experts in assessing ADRs. Assessment is also made independently by the experts available to competent authorities.[417]

New Approach products

The Directives are silent on this issue,[418] except that, as noted above, the medical devices provisions require "a systematic procedure to review experience gained" and independent assessment will be undertaken by competent authorities on information provided to them. It is somewhat curious that there is no regulatory requirement to report adverse information to notified bodies, although the standard form contracts of some notified bodies rectify this by making this a contractual term, at least in relation to medical devices. Notified bodies that audit quality systems may review the files on adverse incidents and complaints during their audits, but this need not legally be either undertaken or extensive. Continuous evaluation is, of course, explicit within quality system standards, where these are adopted.

Cosmetics

Although there is an obligation for the manufacturer (or others) to keep both an "assessment of the safety for human health of the finished product"[419] and "existing data on undesirable effects on human health resulting from use of the cosmetic product", it seems that the safety assessment is a pre-marketing document, so there is no explicit requirement actually to assess the accumulating data.

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416 Directive 2001/83/EC, article 103.

417 See ch 12.

418 It is, after all, theoretically inconsistent with the theoretical position for New Approach products that the pre-marketing controls ensure that the product is safe: this can be illustrated from the machinery Directive requirements that "the aim of measures taken must be to eliminate any risk of accident throughout the foreseeable lifetime of the machinery" (Annex I, para 1.2.2 (b)).

419 which must be carried out by a qualified person with a diploma in pharmacy, toxicology, dermatology, medicine or a similar discipline: Directive 78/768/EEC, article 7a.1(e).

Biocides

As mentioned and discussed further below, the only operative obligation for biocides is to notify the authorities of information which may affect continuing authorisation.[420] The result is to place the formal obligation for assessment of the information on the authorities rather than on the authorisation holder.

GPSD

As discussed at section (b) above, the GPSD is silent as to the procedure of assessment but impliedly requires this in order to satisfy the obligation of notifying the authorities with the result that a consumer product is dangerous. This may, therefore, apply to all consumer product sectors where it is not explicit.[421]

(e) Reporting to the authorities

There are two main purposes in imposing a reporting requirement: firstly, there are situations in which the assessment of safety issues is deemed to be of sufficient importance that it be undertaken by a public authority independently of the manufacturer, usually involving expert scientific or technical input (as with medicinal products and medical devices); secondly, the imposition (as under the 2001 revision of the GPSD) of a horizontal reporting requirement is an incentive for producers to observe all their other post-marketing obligations and as a means of providing an opportunity for the authorities to check post-facto that they have in fact done so. Both these aspects have theoretical justification as regulatory cures for market operators' anticipated failures.[422]

Consistent with what has been said above, there are two broad approaches. One approach requires that *data* on individual events is reported, which is then aggregated and evaluated in order to reach a conclusion, where appropriate, that a safety issue has been identified and that a question arises over whether action should be taken. The other (GPS) approach requires reporting of the *conclusion* that the product has been recognised to be dangerous. An important difference between the two approaches is, therefore, that the former system places the primary *responsibility* for evaluation of new safety information, and of any action that may require to be taken, on the authorities, whereas the latter system places the obligation on manufacturers (and distributors).

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420 Directive 98/8/EC, article, 14.
421 Discussed at the end of this ch.
422 See ch 17.

Under the former system, the issues that arise are: what information should be reported to a regulatory authority, and how soon? Under the second approach, the issue is: on what criteria is the decision to be taken that the product is *legally* dangerous. Under both systems, there is an issue of to which authority or authorities reports should be made.

Medicinal products, medical devices and biocides

The reporting obligations for medicinal products and medical devices are noted in Appendices . The obligation is to report *adverse events.* For medicines, serious suspected adverse events must be reported immediately, and other adverse events are reported periodically. For medical devices, reports must be made immediately of:[423]

> (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
>
> (ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in (i) above to systematic recall of devices of the same type by the manufacturer.

The holder of a biocide authorisation is required to:[424]

> "immediately notify the competent authority of information of which he or she is aware or of which he or she may reasonably be expected to be aware concerning an active substance or a biocidal product containing it and which may affect continuing authorisation. In particular, the following shall be notified:
>
> - new knowledge or information on the effects of the active substance or biocidal product for humans or the environment,
> - changes in the source or composition of the active substance,
> - changes in composition of a biocidal product,
> - development of resistance,
> - changes of an administrative nature or other aspects, such as the nature of the packaging."

It will be seen that the biocide notification obligation involves a wide general duty (anything which may affect continuing authorisation; any information which he should reasonably be expected to be aware), supplemented by expansions in relation to specific risks.

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423 Directive 93/42/EEC, Annex II, para 3.1, 7th indent.

424 Directive 98/8/EC, article 14.

Cosmetics, and other New Approach products

There is no explicit reporting obligation, save that the new GPS obligation may apply. For cosmetics, there is a passive obligation to keep the controlled information "readily accessible to the competent authorities".[425]

It is curious that there is no regulatory obligation under any New Approach Directive for a manufacturer to report adverse events to his notified body. This gap has in practice been filled by the inclusion by many notified bodies of a reporting obligation in their standard terms and conditions of contract, but there is a case for this to be a regulatory obligation, since notified bodies have a regulatory and surveillance role and there is no good reason to exclude them from access to information which may affect their future decisions on certification or audit. The argument that it is only competent authorities that are responsible for market surveillance ignores the reality of the on-going function of notified bodies.

GPS products

In contrast, the GPSD is [he only Directive that makes specific provision for a producer (and also a distributor) to notify a competent authority of the conclusion that a dangerous *product* has been placed on the market. The explicit obligation is:

> "Where producers or distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States thereof under the conditions laid down in Annex I, giving details, in particular of action taken to prevent risk to the consumer."[426]

The obligation is, therefore, triggered by two facts (a) either a subjective conclusion by the individual producer or distributor, or an objective conclusion on the basis of the available information and the level of expert knowledge that he ought to have had the relevant knowledge, that (b) the product does, as a matter of fact, pose risks that are incompatible with the general safety requirement (which is tantamount to saying that it is, legally speaking, unsafe).[427]

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425 Directive 76/768/EEC, article 7a.1.

426 Directive 2001/95/EC, article 5.3.

427 The fact that the risks that are recognised to have arisen in the post-marketing situation are to be compared to the general safety requirement, which, as discussed in ch 8, requires consideration of the test that justified the initial marketing of the product, namely assessment of the minimum risks that are considered to be acceptable with the product's use, strongly supports the view that it would be good practice for the producer

Various procedural problems arise. First, should authorities in all or some Member States should be informed? Annex I of the GPSD[428] states that the information must be given to all member states in which the product is or has been marketed or otherwise supplied to consumers. A potential problem is that the producer might not be aware of the fact that a product has been distributed or taken into a specific Member State. This situation underlines the fact that the notification obligation applies to distributors as well as producers, but not all distributors might be aware that there is a problem that should be notified.

Secondly, this situation raises a more serious problem, which is that of the possibility of multiple, inconsistent and confusing notifications which may arise from the blanket imposition of a notification obligation on the producer[429] and all distributors. This may give rise to different information being notified by different people at different times. Equally, the fact that the information has to be notified to multiple competent authorities[430] gives rise to considerable duplication and to the opportunity for each authority to react differently, whether by requesting different further information or by suggesting or requiring different action. Overall, it is not difficult to foresee serious inefficiency and inconsistency in this system. The issue of whether reports need to be made to more than one authority, whether in different member states or a centralised agency or the Commission is discussed further at chapter 12.

Precisely these problems arose in the early days of both the medicines and medical devices vigilance schemes, and the solution in each case was to provide for single primary notification points on both the commercial and regulatory sides. In other words, the producer should have primary responsibility for notification to a single authority. It would follow that the producer should have an obligation to ensure, as far as he can, that he is in possession of all information from others in the chain of distribution, and that distributors have matching obligations to notify the producer - not

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to undertake a pre-marketing risk assessment and to document the use, benefits and risks at that stage, so that any subsequent increase in risk can be assessed against the background of relevant data.

428 The Annex provides that the Commission is required to define the content of and draw up the standard form of notifications, and put forward simple and clear criteria for determining the special conditions, particularly those concerning isolated circumstances or products, for which notification is not required. (This has not yet occurred.) In the event of serious risks, the information provided shall include at least:(a) information enabling a precise identification of the product or batch of products in question; (b) a full description of the risk that the products in question present; (c) all available information relevant for tracing the product; (d) a description of the action undertaken to prevent risks to consumers.

429 and under Directive 2001/95/EC, article 2(d) more than one company may qualify as a producer, namely the manufacturer, own brander, Community representative or importer, and any professional in the supply chain whose activities have affected the safety properties of the product.

430 not only one authority in each state, but some states such as Germany and UK have multiple local authorities.

primarily their local regulator, save in emergency situations. In fact, such vertical notification obligations are already provided for.[431] Equally, the primary authority should have an obligation to notify the relevant information to all other authorities and the Commission, matched by an obligation on them to forward information to the primary authority. The primary authority would also have decision-making powers which other member states would give effect to on the mutual recognition principle.[432]

In any event, the current bare GPSD obligations requiring multiple notifications by multiple operators to multiple authorities is simply illogical and bound to be found to be unsatisfactory over time.

Reporting incidents that occur outside the Community

A further issue is whether information should be reported to an authority in state A when the adverse event in question has occurred in state B? As we have seen, GPSD is silent on this issue, merely providing that notification must be made if the result is that products on the Community market are dangerous. The same approach is taken by medical devices guidelines (the Directive provisions, noted above, are somewhat ambiguous), which specify that if incidents occur outside the EEA lead to corrective action relevant to CE-marked devices which are offered for sale or are in use within the EEA, then manufacturers should notify the relevant EEA authorities.[433] For medicines, all suspected serious and unexpected adverse reactions occurring outside the Community should be reported.[434]

(f) The decision

Each of the activities discussed above is primarily concerned with process, but the crucial substantive issue is whether there is a regulatory requirement for a decision to be taken that the available information requires that the product is no longer considered to be acceptably safe and that specific action should be taken is the crucial substantive issue. The main issues that arise are: On what criteria or value systems are the decisions to be based (a) that the product is no longer safe,[435]

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431 Directive 2000/95/EC, article 5.1 and 5.2.

432 Whether this would be observed remains to be seen. Experience with medicines on mutual recognition of regulatory decisions is not encouraging: see [chapter].

433 *Guidelines on a Medical Devices Vigilance System*, European Commission, 2001, MEDDEV 2.12-1 rev 4, para 1.3.

434 Directive 2001/83/EC, article 104.

435 This is largely considered in ch 12.

(b) that the manufacturer should take action, and (c) that specific action should be taken? What are the options for action and what response would be appropriate? Is proportionality relevant?

As discussed above, the regulatory regimes fall into two categories, depending on whether the post-marketing obligation to evaluate the safety of the product is placed on an authority (medicines, biocides) or on the commercial operators (GPSD). In practice, manufacturers under the former systems expect, and are expected, to take spontaneous action in proposing changes to the authorities,[436] and to be involved in a constructive dialogue with the authorities. Indeed, the 2001 GPSD specifies that producers and distributors shall cooperate with the authorities (albeit at the request of the authorities) on action taken to avoid risks:[437] it may well be considered good social policy for an obligation (or at least guideline) on collaboration to be promulgated generally.

Criteria for decision

Perhaps surprisingly, the criteria for taking post-marketing action are unspecified in almost all Directives. The GPS provides that:

> "... producers shall adopt measures characteristic with the characteristics of the products which they supply, enabling them to:
>
> (a) be informed of risks which these products might pose;
>
> (b) choose to take appropriate action including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers.
>
> [Such action] shall be undertaken on a voluntary basis or at the request of the authorities... Recall shall take place as a last resort, where other measures would not suffice to prevent the risks involved..."[438]

These provisions in fact avoid the issue of criteria. The basic obligation is for the producer to adopt measures so as to be informed of risks with the product and to be able to take action, that is, to have a vigilance system. He may *choose* to take action, although this is subject to an obligation actually to *take* action voluntarily, without being forced to do so. Such action must be *appropriate*, but when and to what it is appropriate is unspecified. The specific actions of withdrawal, warning and recall are triggered where it is "necessary to avoid" the risks which products might pose. This is wide enough

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436 Directive 2001/83/EEC, article 35 and Commission Regulations 1084/2003 and 1085/2003 for variations of medicines; Directive 98/8/EC, article 7.2 and 7.5 for requests by a biocide holder for cancellation or modification of an authorisation.

437 Directive 2001/95/EC, article 5.4.

438 Directive 2001/95/EC, article 5.1.

to encompass *any* risk, however insignificant, although, firstly, the recall trigger is expressly only appropriate as a last resort and, secondly, words at the start of the article quoted above may be relevant, which refer to risks that are not immediately obvious without adequate warnings. It can be concluded that these GPS provisions are far from clear as to the criteria that apply to when post-marketing action should be taken.

Furthermore, the obligation to adopt measures (to have a vigilance system) is "within the limits of [each individual producer's] respective activities". This is a proportionality limitation, meaning that the extent of a producer's system depends, "commensurate with the characteristics of the products which they supply", on the type of products involved, and the extent to which his activities affect the safety aspects of their products. It might mean that his obligations are limited by the extent of his resources, but probably does not.

New Approach products

All New Approach Directives are silent as to criteria for taking post-marketing action. The medical devices Directives, as noted above, refer to "[applying] any necessary corrective action" and to recall but are silent on when these should be done.

Conclusions

Should the post-marketing criteria for action necessarily be the same as the pre-marketing criteria for placing the product on the market? For the reasons discussed, this is illogical for products such as medicines, for which the pre-marketing requirement is a predicted level of safety and the post-marketing requirement is to assess that the benefit-risk balance remains favourable. Should not the post-marketing test for taking action for other products merely be that the product is now considered unsafe?[439]

Options for action

What action should be taken in particular circumstances? This can be an extraordinarily difficult decision in practice and no further help is given in law or official guidance. It is suggested that the basic issue is to decide what action is appropriate and proportionate in order adequately to prevent the risk. This involves consideration of the nature, incidence and severity of the risk and of what

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439 See ch 19 for discussion of the meaning of safety.

measures would in practice be sufficient to prevent it.[440] However, it is arguable that a lesser goal than prevention is appropriate, such as that all that is required is that proportionate steps should be taken to reduce the risk. Given the range of possible actions that might be taken, it might be logical for each of these to be triggered by separate criteria, but it would seem to be impossible currently to specify such criteria, given the absence of a sophisticated matrix of risk-acceptability criteria.[441]

There is a range of options which are open to a producer in practice, including[442]

(1) taking no action because the risk is so small or any further action would be ineffectual;

(3) continuing to monitor the situation, either passively as more information comes to light, or by actively seeking further information or to verify or investigate further existing information;[443]

(3) restricting the availability of the product;[444]

(4) amending the product information so as to give further information or a warning or contra-indication about use in particular circumstances or about the possibility of encountering specified untoward events;

(5) in the case of certain products involving unavoidable hazards, e.g. medicinal products, pesticides, etc., a restriction on the availability of particular products to specialist intermediaries;

(6) a special notification of a new hazard direct to all users[445] or outlets or specialist intermediaries;[446]

(8) discontinuation from sale of further items of a particular batch or class, where the continued safety of the product in use cannot be guaranteed, even with appropriate warnings;

(8) withdrawal from the distribution network;

(9) recall of products from consumers who have purchased them;[447]

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440 See ch 9.

441 See ch 9.

442 see C Hodges, M Tyler and H Abbott, *Product Safety* (Sweet and Maxwell, 1996), chapter 10 and recall guidelines noted, and also *Recall Procedures for Unsafe Products sold to the Public* (OECD, 1981); *Consumer Product Recall: A Good Practice Guide* (Department of Trade and Industry, undated); *Product Recall Guidelines* (British Retail Consortium, 2003).

443 as with undertaking Phase IV studies with medicines: see chapter .

444 usually for medicines, increasing the legal status from General Sale List to Pharmacy to Prescription Only.

445 Especially where details of users are available electronically and there is confidence that most or all users are known, such as through vehicle licence registers.

446 Distributor networks, or "Dear Healthcare Professional" circulars.

447 Directive 2001/95/EC, article 2(f) defines recall as any measures aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor. In contrast, US legislation adopts a wider and more confusing definition. The policy for post-marketing consumer product safety in USA places considerable emphasis on recall alone as an effective mechanism: Consumer Product Safety Act 1972, 15 U.S.C. ss 2051-2084.

(10) sending an engineer to inspect/modify the product in situ;

(11) advising consumers to dispose of the product and not use it.

Any one (or more) of the last seven of these options may be capable of falling within the scope of the producer's legal obligations. Selection of the option which is appropriate in the circumstances is difficult without further criteria in the Directive itself. Judgment has to be exercised by producers to decide what is necessary, in the context of the particular risks that have been identified, "to avoid those risks"[448]. This should not mean total elimination of *any* risk, and it is implicit that what is intended is that the steps should render an otherwise dangerous product a "safe product" within the meaning of the Directive i.e. one that does not present any risk *or* only the minimum risks compatible with normal and reasonably foreseeable conditions of use[449].

Safety proportionality

In general, it might be argued that a principle of safety proportionality should apply. Thus, the higher the risk, the more serious the action that should be taken, but this is a considerable generalisation. Ideally, in order to assess the *incidence* of the risk, one needs statistics on the number of such products in use (denominator) and the number which might give rise to the safety hazard (numerator). Such statistical data is rarely available. It may be that little of use might be done in order to avoid even a risk of high incidence or severity. One should normally start from the proposition that the higher the *severity* of the hazard, the more serious is the action that should be taken.

Cost proportionality

The question arises of whether the cost of implementing any particular steps carries (if any and, if so, what) weight in determining if the producer is under a duty to act. The obligation to take appropriate action is, like that of providing information, qualified as being "within the limits of the producer's activity" so, as has been suggested above, the economic factor is arguably a material consideration. Nevertheless, the fact that action may be very expensive will undoubtedly carry little weight if the risk of injury posed by the product is a serious one. The civil cases in which this particular issue has been

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448. A DTI official speaking at the CBI/McKenna & Co General Product Safety Seminar, in March 1994 commented that: *"It would not be possible for the Government to try to prescribe in detail what every producer of every product should be doing to comply with these duties. So it will be the producer's job to assess the appropriateness of these or any other measures that might be desirable, because he is the person who is best placed to know what is reasonable and practical in the light of what he knows about this products".*

449 See the General Product Safety Regulations 1994, Regulation 2.

considered indicate that the safety of consumers subjugates considerations of costs for the producer of taking necessary action and potential damage to his market share and the product's reputation.[450]

It is suggested that there is neither safety-proportionality nor cost-proportionality in taking action to the extent that it is objectively unlikely to achieve the appropriate safety result. For example, it would be relevant to take into account the practicalities of available methods of contacting consumers. Some manufacturers have databases with the contact details of all users but others do not, and this is usually related to the differing types of product involved (eg rare capital equipment owned by few or cheap, widely-held consumer goods). If a manufacturer is unable to contact all users it would not seem reasonable to hold him responsible, but this will depend on the type of products involved and whether he could reasonably be expected to have taken steps at an earlier stage to put in place reasonable mechanisms to contact users of his products. There will be scope for development of good practice standards, such as that:

- for vehicles, all users are registered with a governmental agency;
- for white goods (household electrical) and consumer electronics, users should be encouraged to return warranty and registration cards to manufacturers. There is also a developing trend to issue smart cards to consumers. Contact details will increasingly be held through internet purchasing, but consumers may then move email addresses.

A manufacturer who has no means of communicating directly and urgently with a sufficient number of users usually only has the option of making a public announcement in the media. There are certain disadvantages with public announcements. First, they may still not reach all users, either at all or in sufficient time. Secondly, they may have the opposite effect to that desired and even create public alarm.[451] Third, there is often an issue in practice over how much it is reasonable to spend in public advertisements: one can always do more, but there is a limit to what should reasonably be expected, since there will be different return and response rates for different products based upon different consumer behaviours: some consumers will throw away cheap products not return them, some consumers will ignore messages.

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450 *Walton v British Leyland* (1978) unreported; *Carroll v Fearon* [1999] ECC 73.

451 See ch 9 re perception.

(g) Implementing action

A duty on the producer positively to take voluntary action on safety issues was added to the GPSD in 2001, as referred to in section (f) above. This is the only regulatory system that has such an obligation, as the other vertical systems that have obligations to have a post-marketing system do not take the further step of actually requiring action to be taken where relevant. This is a curious omission, although it could be said that it would not fit the medicines system entirely, since that is based on the premise that alteration of the authorised conditions for marketing is subject to approval by the competent authority. It is true that marketing authorisation holders are required to bring to the attention of the authority certain changes in relevant information, noted in section (b) above.

Conclusions on the imposition of post-marketing obligations on producers

First, responsibility for post-marketing safety rests with the authorities for some products (medicines, biocides) but for other products it is to some extent shared between manufacturers and the authorities, as will be seen in the next chapter. Secondly, the safety criteria which would trigger post-marketing action are generally absent or vague under most regimes.

Table 7 identifies whether the various regulatory regimes specify the sequence of framework requirements for manufacturers identified above. There are clearly significant gaps in some regimes in what might be expected to be broad obligations. The omissions can partially be explained as a result of the differences in approach of different regimes, under which it is assumed that certain behaviour will occur. The above analysis demonstrates that the approaches adopted in the various legal measures have some similarities but many differences and sometimes consistencies and omissions. It may be wrong to expect that all systems should adopt exactly the same individual requirements, in view of differences in the nature of products and issues of proportionality. These considerations would explain why the approach adopted for, and particular requirements of, medicinal products differ from, say, toys. The former involves a far more pro-active approach since, as discussed at chapter 4, the pre-marketing evaluation of safety is provisional and needs to be permanently re-assessed so there is a positive need to seek and evaluate new information, whereas this is not the case for almost every other type of products and their system are reactive to such information that arises.

However, if the sequence of steps that we have identified above, or something like it, is accurate in identifying the basic activities that producers should in fact be expected to take in order to operate an effective post-marketing safety system, one may wonder why the legislation for many sectors does not specify that these basic steps should be taken. Sometimes the points are implicit, but it is curious that these broad, simple obligations are not explicit. The fact that post-marketing activities are increasingly thought as a matter of policy to be important and to require the imposition of regulatory requirements is strongly illustrated by the imposition of fairly extensive obligations on producers, distributors and authorities in the 2001 amendments to the GPSD.

It might be argued that one does not need to specify in detail each and every step that producers should take, and that it is preferable to permit flexibility as between different product types, on the basis of appropriateness and proportionality. Equally, it is true that the approach adopted by the GPSD amendments is to impose generalised obligations to have a system that is proportionate to the circumstances but that ensures the *result* that product safety will be continuously reassessed. However, the extended GPS requirements are in some respects frustratingly generalised, since producers and distributors like to know exactly what they are expected to do if criminal sanctions are to be imposed for breach, and clarity is a good legislative principle. The phrases in Article 5 of the GPSD "within the limits of their respective activities" and "commensurate with the characteristics of the products which they supply" are very general and, given the wide range of product sectors to which they apply, will need to be interpreted either by case law or guidelines for each sector.

It might also be argued that it is not necessary to specify each individual step that producers need to take but only the critical steps in the process, such as notification to the authorities, since that is all that is necessary to bring about compliance in fact with the more detailed steps, and enable reasonable regulatory supervision. Two answers to this are the clarity-of-criminal-obligations and clarity-so-as-to-avoid-confusion points just mentioned. Another possible argument, if it is factually justified, would be based on empirical evidence that the system is permitting too many unsafe products to remain on the market that should have been removed by post-marketing action.[452]

Specific criticisms that can be made of the existing legislation are that the New Approach and cosmetics systems include almost no post-marketing requirements. It might be argued that this has been remedied in part by the fact that the GPS post-marketing obligations apply to consumer

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452 Relevant statistics are included in Appendix 2 et seq and discussed at chs 19 and 20.

products otherwise covered by these other vertical systems, but the exact overlap between these provisions is confusing, and the Directorate-General for Enterprise, at least,[453] considers that since New Approach directives "regulate all aspects of safety and categories of risk relating to products to which they apply, the safety requirements of the [GPSD] do not apply to those products.[454] The analysis above would, however, indicate that that view is incorrect, that there are significant gaps in New Approach Directives in post-marketing obligations on producers (and no obligations on distributors), and that therefore some GPSD obligations do apply to such products. The assumption that logically underlies that Directorate-General's approach is that no post-marketing obligations are required for New Approach products since the pre-marketing requirements ensure that such products are safe when put on the market: this is highly questionable, and contrary to the inclusion of the Safeguard clause mechanism,[455] vigilance requirements for medical devices, and continuous reassessment provisions within ISO 9000 series standards.

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453 Personal communications with officials in the Directorate-General for Consumer health and Safety (SANCO) indicate that DG Enterprise's view is not necessarily shared.

454 Communication from the Commission: Enhancing the Implementation of the New Approach Directives, COM(2003) 240, 7.5.2003, para 2.5.5.

455 See ch 12.

12. THE ROLE OF AUTHORITIES IN POST-MARKETING SAFETY

A. PURPOSE OF POST-MARKETING ACTIVITIES BY AUTHORITIES

The purpose of post-marketing control by authorities

The issue for this chapter is what the role of the authorities should be in achieving the safety of products in use after they have been put into circulation, and the extent to which they currently fulfil this role within the existing legislative framework. Classic regulatory theory is that a market requires a regulator so as to correct excessive behaviour by uncontrolled economic operators.[456] However, regulators have wider functions in some product systems.

It has been seen that in some product systems, such as for cosmetics, New Approach and general consumer products, the essential role of the authorities is market surveillance and enforcement, so as to make sure that producers and distributors fulfil their obligations, and that products are safe. For medicinal products, the Commission, the EMEA and national authorities not only have the "classic" regulatory powers in relation to manufacture and wholesale dealing but have continuing primary responsibility, instead of producers, for the continued authorisation for marketing of products. Authorities also play an extension of the traditional role in relation to cosmetics[457] and biocides,[458] by specifying the lists of approved or disapproved substances that may be used and their conditions of safe use, and in relation to tobacco by specifying maximum tar and nicotine yields and labelling information.[459]

The structure of this analysis

This structure of this chapter is as follows. First, a framework of five core activities is suggested which, individually and collectively, would contribute to product safety, and which could be undertaken by competent authorities. The extent to which each activity is found in the vertical and horizontal legislation is then examined, and conclusions are drawn.

The essential finding is that only the 2001 GPSD includes a general framework of obligations on Member States to have significant post-marketing systems and powers. These GPSD provisions will, however, apply to all other consumer product regimes. The only provision that is common amongst all systems (except the tobacco legislation) is a power for the Member State authorities to remove a dangerous product from the market, which is known as the "Safeguard Clause". Of the New Approach Directives, only the Toys Directive touches in more detail on market surveillance issues, and this briefly:

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456 See ch 17.
457 Directive 76/768/EEC.
458 Directive 98/8/EC.
459 Directive 2001/37/EC.

it is arguable that such provisions oust the GPSD provisions, in which case the Toys Directive provisions should be removed in favour of the more extensive GPSD regime.

Extensive experience of how to operate a post-marketing system is available from the Pharmacovigilance System, to which the recent Medical Devices Vigilance System could add. However, the evidence is that the systems for medicines, New Approach, cosmetics, biocides and GPSD are developing along independent lines, and both the legal frameworks and practical experience of each regime remain largely unintegrated. Further findings are that the Pharmacovigilance and Medical Devices Vigilance Systems are largely voluntary and without much legal underpinning, and there are gaps in the authorities' regulatory powers, such as powers to suspend or withdraw centrally authorised medicines.

At a practical level, it is unclear how many aspects of the GPSD requirements will work. Considerable assistance can be gained in understanding the principles and practice of effective post-marketing vigilance by studying the two systems that currently exist, namely the pharmacovigilance system for medicinal products and the medical devices vigilance system. The former has grown from modest beginnings over 30 years and the latter was established when the devices Directives were introduced in the mid-1990s. A feature of both these systems is, however, that they are largely voluntary and the legal underpinning in each case is patchy.

A suggested framework for post-marketing activities of authorities

It is suggested that there are various aspects that a public authority can add to the activities of economic operators in achieving safety in the post-marketing situation:

(a) *verification:* checking that economic operators have correctly and adequately carried out their functions and obligations, both pre-marketing and post-marketing;

(b) *market surveillance:* identifing those products that have been placed on the market and are in use that are unsafe, so that steps can be taken to avoid or minimise any injury that they may cause;

(c) *taking action:* ensuring that appropriate action is taken when safety issues are identified, so that the safety of users is subsequently maximised;

(e) *collaboration:* sharing information with other regulatory authorities, economic operators and consumers/users.

(f) *enforcement:* imposing sanctions, or proposing to courts the imposition of sanctions on economic operators for non-compliance with legal obligations.

These aspects will be examined in turn. It might also be argued that authorities should exercise further functions, such as providing public information such as through vigilance information databases,[460] or reviewing the effectiveness of legislation and guidelines and revising them. Directives often require the Commission to review them and report to the Parliament and Council, frequently at five-yearly intervals.

B. VERIFICATION OF COMPLIANCE

Cosmetics, Biocides, Tobacco and New Approach products

In each of these sectors, subject to a point made below about biocides, the involvement of competent authorities in post-marketing surveillance is purely through the Safeguard Clause, which is discussed at section D below. There is, therefore, no explicit requirement for Member States to check, or have powers to check, that manufacturers or others are otherwise complying with their obligations, although at least some member states have such powers under national legislation.[461] It is, of course, arguable that the absence of such powers in New Approach measures is filled by Chapter IV of the GPSD but this is by no means clear.[462]

Medicinal products

Verification by the authorities that the pre-marketing requirements have been satisfied is inherent in the authorisation regimes for medicinal products and biocides:[463] no further retrospective checks are specified, such as that the source data has been properly generated.

In the post-marketing situation, Member States are required to take all appropriate measures to ensure that the holders of marketing authorisations and, where appropriate manufacturing authorisations, furnish proof of the controls carried out on their medicinal products and/or ingredients and intermediate stages of manufacture, in accordance with the methods that they described in their approved marketing authorisations.[464] Specific provisions apply in relation to live vaccines, immunological medicinal products, and medicinal products derived from human blood or human plasma.[465]

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460 The only such provision is that information on product risks shall be available for GPSD products: Directive 2001/95/EC, article 16.

461 For example, the Consumer Protection Act 1987, s 18, 28, 29.

462 The argument is based on interpretation of Directive 2001/95/EC, Article 1.2. As discussed at ch 12, this author believes that the argument is correct.

463 There are no further verification provisions for biocides.

464 Directive 2001/83/EC, article 112.

465 Directive 2001/83/EC, articles 111.2, 113, 114, 115.

The competent authority of each Member State is required to ensure, by means of repeated inspections, that the legal requirements governing medicinal products are complied with.[466]

> "Such inspections shall be carried out by officials representing the competent authority who shall be empowered to:
>
> (a) inspect manufacturing or commercial establishments and any laboratories entrusted by the holder of the manufacturing authorisation with the task of carrying out checks pursuant to Article 20 [that manufacturers and importers are able to manufacture a product in accordance with the particulars and documents that form the basis of approval of the marketing authorisation];
>
> (b) take samples;
>
> (c) examine any documents relating to the object of the inspection ...."[467]

After every inspection, the officials are required to report on whether the manufacturer complies with the principles and guidelines of good manufacturing practice, and to communicate the contents of their report to the manufacturer.[468]

The above general provisions are supplemented by explicit provisions dealing with powers in relation to those who hold manufacturing and wholesale distribution authorisations, even if the precise nature of the powers is sometimes to be implied. Applicants for manufacturing authorisations for medicinal products are subject to prior inspection of sites and to assessment of their systems as revealed by a data review.[469] The resulting information held by the authorities forms the basis of any subsequent inspections that are carried out. It is not the function of the authorities to check all individual products as they are produced: this responsibility is delegated to the manufacturer's "qualified person", who has personal regulatory responsibilities.[470] The Member State authorities are required to have access to the manufacturer's premises at any time,[471] to take all appropriate measures to ensure that (a) the manufacturer has permanently and continuously at his disposal at least one qualified person,[472] (b) the qualified person carries out his stipulated responsibilities, including control of each batch produced or imported[473] and all other duties.[474]

There are explicit obligations on Member States to take all appropriate action to ensure that only medicinal products in respect of which a marketing authorisation has been granted are distributed in

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466 Directive 2001/83/EC, article 111.1.
467 Directive 2001/83/EC, article 111.1.
468 Directive 2001/83/EC, article 111.3.
469 Directive 2001/83/EC, article 42.
470 Directive 2001/83/EC, articles 48 – 50.
471 Directive 2001/83/EC, article 46 (d).
472 Directive 2001/83/EC, article 48.1.
473 Directive 2001/83/EC, article 51.1.
474 Directive 2001/83/EC, article 52.

their territory,[475] and to ensure that the wholesale distribution of medicinal products is subject to the holding of an authorisation.[476] Member States are required to carry out checks on authorised wholesale distributors.[477]

General consumer products

Since consumer products covered solely under the GPSD are not subject to any pre-marketing verification by an authority, there is strong emphasis on market surveillance and enforcement. Member States are required to

> "establish or nominate authorities competent to monitor the compliance of products with the general safety requirements and arrange for such authorities to have and use the necessary powers to take the appropriate measures incumbent upon them under this Directive."[478]

C. MARKET SURVEILLANCE

The purpose of market surveillance

The purpose of post-marketing surveillance by the authorities both of the market and of information on the use of products is to identify products which are, or are likely to be, unsafe in use, so that steps can be taken to avoid or minimise injury or death which they may otherwise cause. Products so identified may be either those that should have been identified before marketing as potentially or actually unsafe, or those that could only be identified as unsafe after marketing. Any product might fall into the former category if there is a failure in the pre-marketing controls and safety assessment. Some products, such as many medicines, will inevitably fall into the latter category. From the safety perspective, the purpose of identifying products which are unsafe in use is two-fold: it is so that steps can be taken to protect the public from injury which might be caused, first, by those products and, secondly, by other identical or similar products, whether they have been marketed or not.

The rationale for market surveillance stated in the Commission's New Approach Guide places strong emphasis on internal market trade: securing safety is not even mentioned explicitly in the Guide but is implicit within the references to "a high level of protection". The Guide first states that enforcement of Community legislation is an *obligation* of Member States arising out of the requirement of Article 10 of the EC Treaty, which requires member states to take all appropriate

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475 Directive 2001/83/EC, article 76.
476 Directive 2001/83/EC, article 77.
477 Ibid, article 77.5.
478 Directive 2001/95/EC, article 6.2.

measures to ensure fulfilment of their obligations arising under the Treaty.[479] The Guide states that member states have an *implied* obligation to organise and carry out market surveillance, "in a way that is effective and sufficiently extensive to discover non-compliant products", in order "to protect not only the interests of consumers, workers and other users, but also the interests of economic operators from unfair competition".[480]

The mechanisms of market surveillance

Market surveillance is a generic term and covers a number of possible activities. It is suggested that the following are the principal mechanisms that may be adopted by authorities for market surveillance.[481]

1. Keeping a register of products that have been placed on the market

The problem can arise that the authorities wish to know or verify exactly which products are being used. This might be important, for example, if a safety issue is identified with a particular product that may be relevant in relation to other similar products and it is important to be able to identify them and their manufacturers quickly so that action can be taken. Alternatively, the authorities may have identified a dangerous product but may wish to verify who is responsible for it: although labelling details should identify the manufacturer, they may not be available or the product may be counterfeit.

Registration will obviously not be possible without an obligation on a producer or distributor to notify the authorities of relevant details at or before the time when a product is first placed on the market. Such details might be the name and address of the producer and/or person responsible for marketing the product, and details of product identification and product composition. The counter arguments to such a mechanism are that notification may be seen as an exception to the principle of free movement of goods, and that it is expensive to operate, and so disproportionate in relation to safety and cost, so it is not applied to cosmetics, tobacco and other general consumer products.

The issue does not arise with medicinal products since the authorities will have a list of authorised products[482] and authorised marketing authorisation holders,[483] manufacturers[484] and distributors.[485]

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479 See *Guide to the implementation of directives based on the New Approach and the Global Approach* (2000) section 8.1. The Commission notes that authorities should have adequate resources and powers to be able to fulfil these functions, as discussed below.

480 Ibid.

481 See Guide, supra, section 8.2.

482 specifications of final products and even intermediate substance and source materials are to be specified: Directive 2001/83/EC, Annex I. Medicinal products authorised under the centralised procedure are listed in the Community Register of Medicinal Products: Regulation (EEC) No 2309/93, article 12.2.

483 Directive 2001/83/EC, article 8.3.

The same is true for biocides.[486] In contrast, there is a notification requirement before a cosmetic may be placed on the market.[487] The only New Approach Directive to include a notification requirement is that for medical devices, where it only applies to Class I (i.e. low risk) devices or custom-made devices.[488] The rationale for singling out Class I and not the higher Classes was stated to be that in the event that the authorities need to take action if a safety issue arises, they would be able to identify the manufacturers of similar devices in all other Classes through their notified bodies (whose identification numbers are required to be stated on the labelling[489]) but identifying all the manufacturers of Class I products would not otherwise be possible. However, there appears to be a trend towards registration. First, notification provisions were introduced in 1998 for in-vitro diagnostics,[490] and, secondly, for medical devices in Classes IIb and III (but not IIa)[491] Member States may request to be informed of data allowing identification together with the label and instructions for use when such devices are placed on the market in their territory. These provisions are, of course, optional,[492] with the inevitable consequence that there is no uniformity amongst Member States in their implementation.

Notified bodies will have the relevant details for products that they approve or audit, and this covers many new approach products, although there have been calls for the authorities to have the information themselves.[493]

2. Inspecting and auditing operators' systems and documentation

This function has aspects of verification of pre- and post-marketing compliance by operators, which are aspects discussed elsewhere, but also has the function of identifying both data on general levels of safety that are achieved in practice and specific products that are unsafe and have not been previously notified or identified. There is no reason why this mechanism is not appropriate for every product. The authority needs appropriate powers in order to exercise this function, usually with a power of compulsion and ability to prosecute in respect of failures identified. Such powers are not always found in the Community provisions[494] but may exist at national level.[495]

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484 Directive 2001/83/EC, Title IV.
485 Directive 2001/83/EC, article 76.
486 An authorisation is granted under Directive 98/8/EC, article 3.1, with lesser registration provisions for low-risk biocidal products: ibid, article 3.2(i)..
487 Directive 76/768/EEC, article 7a.
488 Directive 93/42/EEC, article 14.1.
489 Directive 93/42/EEC, article 17.2.
490 Directive 1998/79/EEC, article 10.
491 Directive 93/42/EEC, Article 14(1).
492 introduced because Member States disagreed on the need for the provisions, so they were introduced on an option basis.
493 See below in relation to Class I medical devices.
494 They are not even explicit, but are implicit, within the powers listed for general consumer products in Directive 2001/95/EC, article 8.

3. Sample testing and expert safety evaluation of products

Authorities may wish to undertake random or systematic examination or tests on products forwarded to them or obtained by them as test purchases. This should apply to all products.[496]

4. Notifying producers and other authorities of safety information that comes to light

Information may come to the attention of an authority from a range of sources, not necessarily from the producer or distributor of the product in question. It is important that this is shared with relevant producers and other authorities both within and outside the same jurisdiction, including the Commission and relevant Agencies.[497]

5. Investigating adverse events

It may be important that some reports of safety issues or adverse events should be investigated, since the initial information may be inadequate or may need verification.[498] It may be that investigations can be competently carried out by manufacturers or distributors but it may also be that authorities either should carry out this function alone or in collaboration with commercial enterprises, or should have a residual power to do so in the event of a need for verification or failure by commercial operators (and the existence of such a power should itself assist in encouraging compliance).

6. Maintaining a database of safety information

Keeping a record of reliable historic data is an essential requirement for operation of an intelligent ongoing vigilance system, for the authorities as much as for manufacturers, so that not only events but also trends can be identified.[499] This mechanism is well recognised for medicines[500] and medical devices[501] and has been recognised as being appropriate for all consumer products.[502]

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495 For example in the United Kingdom under the Consumer Protection Act 1987, Part II.

496 It is explicit in Directive 2001/95/EC, article 8.1(a)(iii).

497 This is discussed further at ch 20.

498 For the reasons discussed at Appendix 1, it is particularly important that suspected adverse event reports for medicinal products and medical devices are investigated and assessed for their underlying facts and for causation before reliance can be placed on them.

499 This emerged from 2000 as a strong theme in the United Kingdom's new policy approach towards safety within the national Health Service: *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer*, (Department of Health, 2000); *Building a safer NHS for patients: Implementing An Organisation with a Memory*, (Department of Health, 2001).

500 Pharmacovigilance; clinical trials on medicinal products for human use: Directive 2001/20/EC, article 11.

501 Registration of Class I medical devices; certificates of notified bodies for medical devices issued, modified, supplemented, suspended, withdrawn or refused; authorities' vigilance data on medical devices: Directive 93/42/EEC, article 14a, as inserted by Directive 98/79/EC, article 21.

502 This is implicit in Directive 2001/95/EC, articles 6 – 13, especially 9.

Powers of surveillance authorities under the New Approach and for biocides

Notwithstanding the importance placed on market surveillance by the Commission's *New Approach Guide*, quoted at the start of this section, it is somewhat surprising that, of the New Approach family, only the Toys Directive specifies that national authorities are to have particular powers to carry out specific surveillance measures: it provides that the authority shall[503]

(a) carry out sample checks on toys which are on the market, so as to verify their conformity with the Directive;

(b) obtain access[504], on request, to the place of manufacture or storage and to the prescribed information on the basis of which conformity with the Directive was established (including the technical file and type-examination certificate);

(c) have power to ask the manufacturer, his authorised representative or person responsible for marketing the toys established within the Community to supply the above prescribed information within a period specified by the authority; and

(d) have power to select a sample and take it away for examination and testing.

The limited approach also applies to biocides. The only post-marketing provision affecting authorities is that an authorisation for a biocide may be reviewed at any time following new information,[505] and a Member State may, where it considers it necessary on the basis of developments in scientific and technical knowledge, modify the conditions of use, or cancel an authorisation.[506]

Market surveillance obligations on Member States under the GPSD

In contrast, as has been seen above, the general approach in relation to the safety of consumer products under the GPSD is on post-marketing mechanisms rather than pre-marketing controls. It was recognised both prior to the 1992 and 2001 Directives, there was considerable variation between the enforcement measures available in different Member States. Accordingly, the 2001 revision of the GPSD specifies extensive obligations on Member States for ensuring market surveillance, based on the following policy:

> "The safety of consumers depends to a great extent on the active enforcement of Community product safety requirements. The Member States should, therefore, establish systematic

503 Directive 88/378/EEC, article 12. It is, of course, arguable, as noted elsewhere, that the GPSD post-marketing obligations and powers apply.

504 this is an unusually positive formulation in a regulatory measure: a typical power would ascribe power to an authority to obtain access, whereas this obligation is for the authority positively to achieve access: compare the power in Consumer Protection Act 1987, s29 to inspect any goods and enter any premises, other than premises occupied only as a person's residence, for the purpose of ascertaining whether there has been any contravention of any safety provision.

505 Directive 98/8/EC, article 6.

506 Ibid, article 7.

approaches to ensure the effectiveness of market surveillance and other enforcement activities and should ensure their openness to the public and interested parties."[507]

This statement encompasses both market surveillance and enforcement issues: the latter are discussed in sections D and F below. In relation to market surveillance, Member States are subject to the following obligations:[508]

"1. In order to ensure effective market surveillance, aimed at guaranteeing a high level of consumer health and safety protection, which entails cooperation between their competent authorities, Member States shall ensure that approaches employing appropriate means and procedures are put in place, which may include in particular:

(a) establishment, periodical updating and implementation of sectoral surveillance programmes by categories of products or risks and the monitoring of surveillance activities, findings and results;

(b) follow-up and updating of scientific and technical knowledge concerning the safety of products;

(c) periodical review and assessment of the functioning of the control activities and their effectiveness, and, if necessary, revision of the surveillance approach and organisation put in place.

2. Member States shall ensure that consumers and other interested parties are given an opportunity to submit complaints to the competent authorities on product safety and on surveillance and control activities and that these complaints are followed up as appropriate. Member States shall actively inform consumers and other interested parties of the procedures established to that end."

The above wording is, as usual in Community legislation, expressed as broad principles and is short on detail. No systematic attempt has been made to define the precise features, mechanisms and facilities which Member States have or should have. Accordingly, the practice of Member States may develop along different and uncoordinated lines.

Medicinal products: pharmacovigilance obligations for authorities

The pharmacovigilance system[509] is the most extensive, integrated post-marketing system that exists but it is largely voluntary. The system relies on close collaboration between authorisation holders and authorities, and there is little evidence that this does not occur. There are few legal obligations, since the system is largely based on guidelines, and this has the advantage that improvements can be made fairly easily and swiftly: the system has certainly grown considerably in scope, particularly since

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507 Directive 2001/95/EC, recital 24.

508 Directive 2001/95/EC, article 9. One may note careful use of the word "guarantee": this enshrines a policy objective but does not guarantee its delivery.

509 See Appendix 1.

it became formalised in the late 1980s. The Pharmacovigilance System is thought to operate well, but the Commission recognises the need to ensure stronger coordination of national systems through a greater role for the EMEA.[510]

Central amongst the obligations on Member State authorities is to ensure that all suspected serious adverse drug reactions occurring within their territory are recorded and reported immediately to the EMEA and the person responsible for placing the medicinal products on the market, within 15 days of receipt of the information.[511] Under the centralised system, the EMEA has an obligation then to pass the information on to the other Member States.

Conclusions on market surveillance

The Community has recognised that market surveillance is an important function. The pharmacovigilance system can be traced to informal national procedures that began in the 1960s and has been considerably extended and formalised during the 1990s, but it remains largely voluntary and with little legal structure or obligations. The pharmacovigilance approach has been copied from the introduction in the 1990s of medical device regulation by the vigilance system for that sector, which is similarly largely based on guidelines. The 2001 amendments to the GPSD have introduced an extensive post-marketing framework, in which extensive obligations are imposed on Member States to have structures, personnel, budgets and powers.

Given this recent emphasis on post-marketing controls, the absence of more extensive legal frameworks is surprising. If a general legal framework of surveillance requirements is appropriate for general consumer products, there would seem to be justification not only for such a framework to exist for all other products, but also for the same framework to apply for all sectors. Further, it is suggested that the unified framework should provide for most, if not all, of the six specific mechanisms that have been suggested above.

It may be justifiable for some of the six mechanisms to be excluded in the case of particular product sectors. For example, it may be asked why there is a notification obligation for medical devices but not for other product sectors, such as electrical products or toys. One could argue a theoretical case for requiring notification of all products, and the converse case that it is unnecessary and expensive. Bearing in mind the proportionality principle, the rational approach would be to test the case against statistical evidence of situations in which the authorities need to identify and contact producers and

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510 Communication from the Commission: *A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient- A Call for Action* COM(2003) 383, 1.7.2003, section 2.1.

511 Regulation (EEC) No 2309/93, article 23 under the centralised system and Directive 2001/83/EC, article 105.3 under the mutual recognition system.

distributors quickly so as to take action. Such evidence is seemingly publicly unavailable and therefore seems to be lacking. It will be relevant that messages about safety can be quickly disseminated to the public through the media, and the case for registration is thus significantly weakened.

A number of points of good practice have been established by the Pharmacovigilance System which could be applied in other sectors. First, a post-marketing system can only operate effectively if there is close, active collaboration between all the relevant actors. The activities necessary are: reporting the raw data; transmission, collation and verification; experts assessment; deciding what steps need to be taken in response; and implementation of appropriate action. (In the case of medicines, the actors may include doctors, nurses, patients, commercial companies, national competent authorities, the EMEA and the European Commission, and relevant experts.) Secondly, the effectiveness of the system requires comprehensive and reliable data, expert assessment, and experienced judgment. It is advisable to have data that establishes a numerator (how many adverse incidents) and a denominator (how many products in circulation or human exposures). It is necessary to evaluate both the risk posed by the hazard that has been identified and any change in the risk that was previously assessed, for example when the product was first marketed. What is evaluated is the risk/benefit balance of a product, namely whether the incidence and severity of one particular hazard or the basket of hazards associated with use of the product are judged unacceptable given the therapeutic benefits that are anticipated with its use. Finally, there are the practical issues that a vigilance system will operate more quickly if it has greater statistical power (ie if it covers a large population such as that of the Community), and if it incorporates integrated, sophisticated and speedy communication channels. In other words, there must be clear and swift channels of communication and of decision-making.

D. ENSURING APPROPRIATE ACTION IS TAKEN

The purposes

The primary purpose of ensuring that appropriate action is taken is to protect the public from harm that may be caused by dangerous products that either may be on the market or have been sold. The corrective action that will be appropriate in given circumstances will depend on the principle of proportionality[512] and this can pose considerable challenges of judgment in practice. Issues often arise

[512] Guide, section 8.2.2.

of balancing urgency,[513] incomplete data, and the practicality, effectiveness and cost-efficiency of possible different options.[514] It may be sufficient to rectify the non-compliance of an individual product or type, but it may also be necessary to undertake an extensive information campaign and/or product recall.

The horizontal GPSD powers

Powers of competent authorities to take action

The GPSD, as noted above, is the one Directive that places particular emphasis on Member States' post-marketing obligations. It sets out a long and non-exhaustive list of particular measures in Article 8 which enforcement authorities must have power to take and be entitled to take in individual cases:

> "(a) for any product:
>
> (i) to organise, even after its being placed on the market as being safe, appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption;[515]
>
> (ii) to require all necessary information from the parties concerned;
>
> (iii) to take samples of products and subject them to safety checks;
>
> (b) for any product that could pose risks in certain conditions:
>
> (i) to require that it be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of the Member State in which the product is marketed, on the risks it may present;
>
> (ii) to make its marketing subject to prior conditions so as to make it safe;
>
> (c) for any product that could pose risks for certain persons:
>
> to order that they be given warning of the risk in good time and in an appropriate form, including the publication of special warnings;
>
> (d) for any product that could be dangerous:
>
> for the period needed for the various safety evaluations, checks and controls, temporarily to ban its supply,[516] the offer to supply it or its display;

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513 There can be a need to balance considerations of urgency with the need to obtain more, or more reliable, information and to permit commercial operators the due process of discussion on the proper interpretation and appropriate consequences that should be taken.

514 See C Hodges, M Tyler and H Abbott, *Product Safety* (Sweet and Maxwell, 1996); M A Menlowe and A McCall Smith, *The Duty to Rescue* (Dartmouth, 1993); W L Pines (ed), *When Lightning Strikes: A How-To Crisis Manual With Classic Case Studies* (Washington Business Information, Inc., 1994); R Heath, *Crisis Management for Managers and Executives* (Financial Times and Pitman Publishing, 1998); M Seymour and S Moore, *Effective Crisis Management* (Cassell, 2000)

515. The 1992 Council Minutes noted the statement of the Council and the Commission that the characteristics to be checked include the way in which a product behaves when disposed of insofar as such disposal may present direct risks to the health and safety of consumers.

(e) for any dangerous product:

to ban its marketing and introduce the accompanying measures required to ensure the ban is complied with;[517]

(f) for any dangerous product already on the market:

(i) to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents;

(ii) to order or coordinate or, if appropriate, to organise together with producers and distributors its recall from consumers and its destruction in suitable conditions."

Article 8.4 requires and empowers the competent authorities to address their authorised measures, as appropriate, to:

(a) the producer;

(b) within the limits of their respective activities, distributors and in particular the party responsible for the first stage of distribution on the national market; and/or

(c) any other person, where necessary, with a view to co-operation in action taken to avoid risks arising from a product.

The Directive says nothing about who is to bear the costs of taking any of these measures against a supposedly unsafe product in any given case. A personal view by one of the authors of the 1992 Directive was that it would seem logical that national measures accompanying the Directive's transposition should stipulate the general principle that the person responsible for a defect should assume the direct costs of remedying it[518].

Limitations on use of the powers

The Directive does not allow the Member States to use these powers with absolute discretion. The powers as listed in the above order represent a general escalation in the degree of intervention in the market and with the affairs of economic operators. Article 8.2 specifies that when Member States take measures such as those listed in article 8.1, they shall[519]

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516 In contrast, the US Food and Drug Administration has no power to order immediate temporary suspension of marketing of a dangerous device. The available power is to start proceedings to ban a device but this is a process that takes two years as a result of a requirement to hold hearings. Instead, the US authorities have to rely on [powers to order a] [change of labelling], but there is evidence that people do not pay sufficient attention to labelling, and there is concern that labelling used in USA is, for product liability reasons, so extensive as to be of limited and diminishing value in achieving safety.

517. The 1992 Council minutes noted the statement of the Council and the Commission that this provision may lead to a decision to prohibit the manufacture of the product concerned if the health and safety of consumers so require.

518. R. Gielisse, supra.

519 Directive 92/59/EEC article 6 merely required the Member States to have these powers but it seems that under the 2001 Directive Member States have an obligation to take action in appropriate circumstances: recital 22 states that their powers

"act in accordance with the Treaty, and in particular with Articles 28 and 30 thereof, in such a way as to implement the measures in a manner proportional to the seriousness of the risk, and taking due account of the precautionary principle".

It follows that a Member State only has power to adopt a measure in a given case which is, first, proportionate to the seriousness of the risk involved and not disproportionate to it, and, secondly, in conformity with the Treaty, in particular the requirements eliminating quantitative restrictions between Member States. The experience of at least United Kingdom enforcement authorities[520] is that the mere existence of regulatory powers does not mean that measures must be taken by the authorities in every case. The policy is to achieve the objectives of the Directive and in particular the purposes of article 6 (primarily that products placed on the market be safe). The mere existence of regulatory powers can be a powerful encouragement for commercial enterprises to take voluntary action and, in practice, it may not be necessary for them formally to be used so as to achieve the policy objectives. For example, the threat to use powers can act as indirect coercion, particularly in an emergency situation: a recalcitrant manufacturer may well find himself forced to publish a press release at his own expense, about an unsafe product, or to recall a product, against the threat of more extensive and damaging regulatory action.

Indeed, the Directive explicitly requires competent authorities to:

> "encourage and promote voluntary action by producers and distributors, in accordance with the obligations incumbent on them under this Directive, and in particular Chapter III thereof, including where applicable by the development of codes of good practice".[521]

Nevertheless, the competent authorities have an obligation - and therefore retain a residual power - themselves to organise or order the post-marketing measures of withdrawal, alerting consumers or of recall specified in article 8.1(f), "if necessary"

> "if the action undertaken by the producers and distributors in fulfilment of their obligations is unsatisfactory or insufficient. Recall shall take place as a last resort. It may be effected within the framework of codes of good practice on the matter in the Member State concerned, where such codes exist."[522]

It would appear that these provisions seem to require the authorities to have powers[523] to

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"should be applied" when producers and distributors fail to prevent risks to consumers in accordance with their obligations, and article 7 requires member states to take all measures necessary to ensure that the rules on penalties are implemented.

520 Various conversations with officials at the Department of Trade and Industry and trading standards officers.

521 Directive 2001/95/EC, article 8.2, second para.

522 Directive 2001/95/EC, article 8.2, third para.

523 Difficult issues of fairness or human rights may arise over exercise of these powers, under which producers/distributors may seek redress against an authority which exceeds its powers or what is reasonable in relation to post-marketing activity.

(a) order a producer or distributor to implement a warning campaign, withdrawal and/or recall in a certain manner[524] within a specified time;

(b) verify whether the order and conditions have been complied with;

(c) in cases of non-compliance to impose sanctions and/or to order steps to be taken to achieve conformity;

(d) in cases of non-compliance, or possibly in urgent cases, themselves to organise the steps to be taken, by whatever means, to the extent that the producer/distributor does not comply or no longer exists, and to recover the costs from the party who has not complied with an order.

Member States are required to assess the circumstances of each individual case on their merits, taking into account the guidelines referred to in point 8 of Annex II of the Directive, in order to conclude if it is a case where products pose a serious risk. [525] "Serious risk" is defined to mean any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities.[526] In such a case, the competent authorities are to have power "to take the necessary action to apply with due dispatch appropriate measures such as those mentioned in paragraph 1, (b) to (f)."[527]

What measures are "appropriate"?

As discussed at chapter 11, the GPSD does not make clear what measure(s) will be appropriate for a company or a Member State to take - or not take - in any given situation, and on what criteria decisions should be based. There is a series of steps that can be taken, and issues of practicality, reasonableness and proportionality arise.

Article 8.2 requires that Member States shall act in accordance with the precautionary principle. The Directive does not define "the precautionary principle" but some guidance is given in a Commission paper issued in 2000, which treats the precautionary principle as "part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy."[528] The reference to the precautionary principle in article 8.2 was politically motivated[529] and its meaning in practice is uncertain.[530]

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524 This raises difficult issues about what mechanisms are appropriate and what success/return rates are acceptable.

525 Directive 2001/95/EC, article 8.3.

526 Directive 2001/95/EC, article 2(d): this is discussed further below in relation to the RAPEX procedure.

527 Directive 2001/95/EC, article 8.3.

528 Communication from the Commission on the precautionary principle, COM (2000) 1, 26.1.2000. A definition following the same lines is given in Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, article 7.

529 It was included in 2001 at the insistence of the European Parliament, whereas the Commission and member states had preferred either no reference or a reference in a recital: see succeeding drafts of the 2002 Directive. The precautionary principle was endorsed at the Nice Council meeting in December 2000.

530 For a discussion of the precautionary principle in its origins in environmental risk assessment, and recent adoption in food law, see J Scott and E Vos, "The Jurudification of Uncertainty: Observations on the Ambivalence of the

The GPS Safeguard Clause

It has been noted that the principle behind regulatory Directives is that a product that conforms to the general safety requirement is enabled to circulate freely within the Community. However, article 3.4 of the GPSD provides that a product's conformity with the provisions of national law, standards and other factors listed in article 3.2 and 3.3 which are to be taken into account in deciding whether the product conforms to the general safety requirement:

> "... shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market or recall where there is evidence that, despite such conformity, it is dangerous".

This provision is at face value contradictory and it attracted some criticism during the development of the Directive. It is, however, understandable that it survived given that equivalent so-called "safeguard clauses" appear in the New Approach Directives, and that Article 95(5) of the Treaty requires a safeguard clause to be included in harmonisation measures where appropriate: this clause is, essentially, the manifestation of a residual degree of national sovereignty reflecting matters of national interest set out in Article 30 of the Treaty as justifying restrictions on trade between Member States.[531] Whilst the provision may prove to be valuable (for example in enabling action to be taken against mis-use of an intrinsically safe product) there is undoubtedly scope for the unscrupulous imposition of restrictions on exports into other countries in the Community and the clause gives rise to a considerable degree of uncertainty as to how effective the Directive will ultimately be in its stated aim of eliminating barriers to trade and distortions of competition. The exercise of the power will, however, be subject to scrutiny at Commission level (see below).

Commission oversight of national measures

The Commission undertakes an automatic review of all measures adopted by Member States that are not local in effect, whether or not they are emergency measures.[532] The Commission also retains a residual power to adopt its own decision in relation to serious risks in certain circumstances, which requires Member States to take measures.[533] These are examined in more detail below. The powers of the Commission to take direct action against products have been watered down considerably from proposals made before the 1992 Directive. Nevertheless, the Commission still has a role of pivotal

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Precautionary Principle within the EU and the WTO" in C Joerges and R Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford, 2002).

531 It could, for example, leave intact the UK's powers to issue safety regulations under section 11 of the Consumer Protection Act 1987.

532 Directive 2001/95/EC, articles 11 and 12.

533 Directive 2001/95/EC, article 13.

importance involving co-ordination, initiation and decision making on Community-wide action. At the very least the Commission will be highly influential.

Safeguard Clauses in New Approach, cosmetics and biocides Directives

Unlike the GPSD, the Directives dealing with cosmetics, biocides and the New Approach do not specify that competent authorities should be able to require or ensure that any particular action must be taken post-marketing by economic operators, other than in relation to medical device vigilance, and do not state that the authorities are to have any such powers or abilities, other than in relation to themselves taking action to remove non-compliant products from the market through the Safeguard Clause, of which the following is a typical example:[534]

> "Where a Member State ascertains that:
>
> - machinery bearing the CE marking...
>
> used in accordance with their intended purpose are liable to endanger the safety of persons..., it shall take all appropriate measures to withdraw such machinery ... from the market, to prohibit the placing on the market, putting into service or use thereof, or to restrict free movement thereof."[535]

This mechanism is directed towards unsafe products rather than at individuals, so is rightly result-oriented rather than focussed on personal responsibilities. A limitation of the Safeguard Clause is that it cannot generally be invoked against a product that does not bear CE marking.[536]

Medicinal products

Curiously, there are different tests for post-marketing action under the centralised and mutual recognition systems (and the tests differ from the pre-marketing tests). Further, the wording used in the legislation does not reflect actual practice since the test that is in fact used by the authorities is a risk-benefit assessment.[537] It is notable that the following provisions place no discretion on national authorities, requiring them to take action (see the word "shall") where specified factual situations exist.

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534 For the Safeguard Clauses for cosmetics see Directive 76/768/EEC, article 12; and for biocides Directive 98/8/EC, article 32. There is no Safeguard Clause or other market surveillance power in Directive 2001/37/EC which only deals with the manufacture, presentation and sale of tobacco products.

535 Directive 98/37/EC, article 7.1. This is followed by a requirement immediately to inform the Commission of any such measure, after which the Commission shall enter into consultation with the parties concerned without delay and either inform advise the other Member States (but with no compulsion on them to adopt the measure) or inform the originating State that it considers that the measure is unjustified (in which case there is no mechanism for resolution of the conflict).

536 See Guide, section 8.3.1, which lists a number of detailed divergences between Directives in relation to their Safeguard Clause provisions.

537 As recognised in the Pharmacovigilance Guidelines, and partly in Recital 15 to Regulation (EEC) No 2309/93 referred to below.

Under the mutual recognition system, the competent authorities shall suspend or revoke a marketing authorisation where the medicinal product "[a] proves to be harmful in the normal conditions of use, or [b] where its therapeutic efficacy is lacking, or [c] where its qualitative and quantitative composition is not as declared" or [d] where the particulars that supported the application are incorrect, or [e] have not been amended in the light of scientific and technical progress, or [f] where the required manufacturing controls have not been carried out.[538] The authorities are also required to take all appropriate measures to ensure that the supply of a medicinal product shall be prohibited, and the product withdrawn from the market, if any of [a] to [c] or [f] above occurs or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled.[539] The prohibition on supply or withdrawal may be limited to those batches which are the subject of dispute.[540] The competent authority shall suspend the marketing authorisation for a category of preparations where specified manufacturing or importing control requirements are not met.[541]

It is suggested that the "proves to be harmful" test is inappropriate because it is uncertain and contains no comparative element: in theory, a product could be removed if it demonstrated *any* harmful characteristics or adverse events.

For medicinal products authorised under the centralised system, it is stated that a marketing authorisation may not be varied, suspended, withdrawn or revoked except on the grounds, or in accordance with the procedures, set out in Regulation (EEC) No 2309/93,[542] and must state in detail the reasons on which they are based and communicate these to the authorisation holder,[543] but that Regulation curiously omits the range of powers that are stated in Directive 2001/83/EC. It does provide that the "supervisory authorities" shall be the competent authorities of the member state which grants the manufacturing authorisation or into which the product is imported from a third country,[544] and that the supervisory authorities have responsibility for verifying that the person responsible for placing the product on the market or manufacturer or importer satisfies the manufacturing requirements and for exercising supervision over such person as set out in what is now Title IV of Directive 2001/83/EC, which deals with manufacture and importation.[545] If serious differences of opinion arise between Member States as to whether these requirements are being satisfied, the Commission may request a new inspection, which may involve an inspector from another Member

538 Directive 2001/83/EC, article 116.
539 Directive 2001/83/EC, article 117.1.
540 Directive 2001/83/EC, article 117.2.
541 Directive 2001/83/EC, article 118
542 Regulation (EEC) No 2309/93, article 68.
543 Regulation (EEC) No 2309, article 67.
544 Regulation (EEC) No 2309/93, article 16.
545 Ibid, article 17.1. The original referred only to Chapters IV and V of Directive 75/319/EEC.

State.[546] Where the supervisory authorities or competent authorities of any other Member State "are of the opinion" that the manufacturer or importer is "no longer fulfilling the obligations" laid down in what is now Title IV of Directive 2001/83/EC, there is a consultation procedure leading to issue of a Commission Decision, except that a member state may suspend use of the product in its territory where urgent action is essential to protect human or animal health.[547]

These provisions deal with control of manufacturing aspects but one does not find provisions that deal with any test for or powers relating to suspension or withdrawal of a centrally authorised medicinal product on safety grounds. This is an extraordinary omission, particularly since recital 15 to the Regulation explicitly recognises that it is necessary to make provisions for the supervision of authorised products "and in particular for the intensive monitoring of adverse reactions ... through pharmacovigilance activities in order to ensure the rapid withdrawal from the market of any medicinal product which presents an unacceptable level of risk under normal conditions of use". It is provided that the person responsible for placing a product on the market shall bring new information to the attention of the authorities and apply for variations in the marketing and manufacturing authorisations as necessary and in accordance with scientific and technical progress,[548] and this approach, if it is observed, would lead to regular amendments in the statements of the approved and recommended conditions of use, but would not authorise suspension or removal from the market.

As noted above, an authorisation granted under the mutual recognition system may be suspended or revoked where the product proves to be harmful in the *normal conditions of use*, but it is also provided that, although the pharmacovigilance system is intended to ensure the adoption of appropriate decisions having regard to information obtained about adverse reactions under normal conditions of use, the system shall also take into account "any available information on misuse and abuse of medicinal products which may have an impact on the evaluation of their benefits and risks."[549] The "proves to be harmful" test can be criticised as being inappropriate, on the basis that it would appear that it is triggered by evidence of *any* adverse reaction, and it should be replaced by the test that is in fact adopted in practice,[550] which is where the risks are considered to outweigh the potential benefits.[551]

It is also relevant to note that the above provisions refer to suspension from marketing products, or to withdrawing them from the market, but, as has been established in the context of discussions on the

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546 Ibid, article 17.2.
547 Ibid, article 18.
548 Regulation (EEC) No 2309/83, article 15.
549 Directive 2001/83/EC, article 102. See ch 3 for Court of Justice decisions on the relevance of safety in overdose.
550 See the Pharmacovigilance Guidelines.
551 See chs 4 and 19.

GPSD, these concepts do not deal with recall of medicinal products once they have passed the point of supply to a patient/consumer.

E. COLLABORATION WITH OTHER AUTHORITIES: COMMUNITY PROCEDURES ON UNSAFE PRODUCTS

Medicinal products

Collaboration between national authorities, the Commission and the EMEA is intrinsic within both the mutual recognition and centralised authorisation systems, both pre- and post-marketing. The detailed provisions are discussed elsewhere.[552]

New Approach products

New Approach Directives generally provide[553] that immediately after a Member State has taken action against a product under the Safeguard Clause it must notify the Commission of the action and the evidence to justify it. If the Commission considers the action to be justified it informs the other Member States, although there is no mechanism under which the others are obliged to take any action, not object to the position. If the Commission considers the first Member State's action to be unjustified, it shall immediately inform that State, although there is no provision as to what happens then.

The purposes of this procedure are stated to be, firstly, to allow the Commission to analyse the justification of national measures restricting the free movement of goods (a market issue rather than a safety issue) and, secondly, to inform all national surveillance authorities about dangerous products.[554] Surely, the principal justification should be to ensure safety? The well-established history of problems of mutual recognition and differences in opinion on safety issues between Member States over notifications on safety issues with medicinal products would suggest that there may be a need for formal mechanisms, as were introduced for medicines,[555] to reach clear scientific conclusions on the significance of safety information and to reach binding decisions on the removal of products from the market or any necessary mandatory changes in design, production, information supplied and so on.

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552 C Hodges "The Regulation of Medicinal Products and Medical Devices" in I Kennedy and A Grubb (eds), *Principles of Medical Law* (Oxford, 2ed, 2003); ch 4 above.

553 See for example Directive 98/37/EEC, article 7.

554 *Guide on the implementation of Directives based on the new Approach and the Global Approach*, supra, section 8.3.1.

555 See ch 4.

The introduction of similar general mechanisms under the GPSD, as discussed below, reinforces the point.

At the very least, there have been clear calls for better mechanisms for circulation of market surveillance information in relation to more than one important product sectors.[556]

GPSD products

The European Product Safety Network

The 2001 Directive establishes the European Product Safety Network ("the Network") as the mechanism for collaboration between the competent authorities of the Member States responsible for product safety.[557] This followed a finding of the Commission's 1999 review of the 1992 Directive that there existed a problem of coordination between national authorities, and the majority of Member States having more than one ministry involved and some having decentralised systems.[558] The Commission is required to promote and take part in the operation of the Network.[559] The Network is required to develop in a coordinated manner with the other existing Community procedures, particularly RAPEX,[560] and its objective is specified to be, in particular, to facilitate:[561]

> "a) the exchange of information on risk assessment, dangerous products, test methods and results, recent scientific developments as well as other aspects relevant for control activities;
>
> b) the establishment and execution of joint surveillance and testing projects;
>
> c) the exchange of expertise and best practices and cooperation in training activities;
>
> d) improved cooperation at Community level with regard to the tracing, withdrawal and recall of dangerous products".

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556 Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC, COM (2000) 899 final, 26.01.2001, Explanatory Memorandum, section 7, although the proposal (article 19: the Member States shall take the appropriate measure to ensure that the competent authorities cooperate with each other and transmit to each other the information necessary to enable the Directive to be applied uniformly) could be described as being exceptionally aspirational and vague; A H Powell, *Study on the Implementation of the Low Voltage Directive* (European Commission, 1999).

557 Directive 2001/95/EC, recital 24 and article 10.1.

558 *Study on Directive 92/59/EEC*, Centre de Droit de la Consommation, Louvain-la-Neuve, 1999.

559 Directive 2001/95/EC, article 10.1.

560 The Common Position of the 2001 Directive also included an obligation to cooperate with relevant bodies responsible for vertical sectors (relevant bodies in product safety covered by "the legislation referred to in Article 1(2)", which refers to, but excludes from GPSD, other specific legislation). There is no point in duplicating the safety activities of separate networks dealing with consumer products and, say, medicinal products or medical devices, although a case can be made for some collaboration between the bodies involved.

561 Directive 2001/95/EC, article 10.2.

Specific notification provisions

The GPSD specifies three procedures that involve Member States and the Commission in notification of measures, exchange of information and adopting emergency measures. These are:

1. notification of normal enforcement measures taken by a Member State - Article 11;
2. notification through the RAPEX system of emergency measures adopted by a Member State in relation to products presenting a serious risk requiring rapid intervention, and co-ordination by the Commission of appropriate measures in all Member States - Article 12;
3. adoption of a decision by the Commission which requires Member States to take temporary measures in the case of a serious risk requiring rapid action - Article 13.

Conclusion

It was noted at the end of section C above that an effective market surveillance system within the Community needs to include provisions for effective communication and collaboration between national (and frequently decentralised, multiple) enforcement authorities, Member State governmental authorities, the Commission, and any Community-level Agencies and committees which may be necessary. The existence of the GPSD provisions just discussed illustrate the same points. However, the coordination mechanisms that exist are sometimes unspecified in legislation (and, therefore, may in practice be rudimentary, such as for many New Approach regimes, cosmetics, and biocides). Even where they do exist, such as under the GPSD, the system is based on Member State subsidiarity and may in practice not satisfy the need for speed and efficiency of operation.

F. ENFORCEMENT THROUGH SANCTIONS

The purpose of sanctions and justification for harmonisation in enforcement

The purposes of any criminal law are to punish breaches by individuals and to act as a deterrent to others, thereby encouraging compliance and, in this context, safety.[562] Just because there is harmonisation of the rules for the market trading in products, is harmonisation and consistency of member states' enforcement powers, policies and practice important in relation to product safety? We are not principally concerned here with whether there may be legal and political justification, and the

562 See the theoretical discussion at ch 19.

relevance of the subsidiarity principle, although the following arguments for consistency have been put forward:[563]

- It is essential for the proper functioning of the Community that the measures taken by different member states should result in Community law being applied with the same effectiveness and rigour as in the application of their national law;
- The effective and uniform application of Community rules represents a new priority which is essential to the smooth functioning of the internal market. Legal certainty and the credibility of the internal market are at stake.

Community documents rarely refer to a justification for harmonisation in enforcement based on safety grounds, although the adoption of a common approach is implicit within the legislation on medicinal products and, to a lesser extent, the Safeguard Clause system, particularly for medical devices. Development of the New Approach and GPSD systems have recently turned to post-marketing issues, with the Commission asserting in relation to the former that Member States "should achieve a common level of market surveillance activity" but without saying why.[564]

The justification from the safety perspective is in fact simple: variations in enforcement across member states are likely to encourage variations in the safety of products and consumers, particularly where the regulatory requirements include important and complex provisions compliance with which would entail significant cost and non-compliance might raise significant safety issues.

Theoretical considerations would indicate that the main issues and variables that should be considered include:

(a) legal provisions: what authorisation and powers do the authorities have?

(b) mechanisms and resources: what authorities exist, how are they organised and report, how many people and what technical and expert support is there?

(c) finance: what budget is available?

(d) policies: what enforcement priorities and sentencing practice are adopted?

(e) applying experience: which products pose particular problems?

The extent to which these aspects are included in the Community provisions is considered here: aspects of national law are outside the scope of this work, but issues of Community policy arise from national variations.

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563 Decision No 1496/98/EC of the European Parliament and of the Council of 22 June 1998 establishing an action programme to improve awareness of Community law within the legal professions (Robert Schuman project).

564 *Consultation Document Prepared by the Directorate General for Enterprise on the review of the New Approach*, (European Commission, 2001), section 2.5.2.

Member States' discretion on implementation and the Community vacuum

Article 10 (ex 5) of the EC Treaty requires the Member States to take all appropriate measures to ensure fulfilment of the obligations arising out of the Treaty or resulting from action taken by the institutions of the Community. A directive is binding on each member state as to the result to be achieved but leaves to the national authorities the choice of form and methods.[565]

In some fields (for example, customs, indirect taxation, agriculture, foodstuffs and pharmaceuticals) the Council has adopted detailed secondary legislation in respect to the enforcement of the Community law that required Member States to take specific measures but, as has been discussed above, the requirements in relation to pharmaceuticals, for example, merely impose specific obligations on national competent authorities such as to inspect manufacturing sites or operate pharmacovigilance systems, rather than as to the specific criminal penalties, resources and enforcement policies that should be adopted.

When a Community measure does not provide any specific penalty in case of breach, the Member States are competent to adopt such criminal or administrative sanctions as appear to them to be appropriate,[566] save that (a) they must ensure that any infringement is penalised under conditions, both procedural and substantive, which are analogous to those applicable to infringements of national law that are of a similar nature and importance and (b) any penalty imposed must be effective, proportionate and persuasive.[567]

Neither Article 10 of the Treaty nor, for example, a provision in Regulation 3820/85 requiring Member States to adopt the provisions necessary for the implementation of the Regulation relating to rest periods for road transport drivers, requires a Member State to introduce into its national law a specific system of criminal liability, such as the criminal liability of legal persons, in order to ensure compliance with obligations imposed under the Regulation on the undertaking (i.e. road transport

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565 Article 249, EC.

566 Case C-50/76 *Amsterdam Bulb v Produktschap voor Siegewassen* [1977] ECR 137 paras 31-33.

567. Case 68/88 *Commission v Greece* [1989] ECR 2965 paras 22-27; Case C-326/88, *Anklagemyndighedem v Hansen & Sons I/S*, [1990] I E.C.R. 2911; Case C-36/94 *Siesse v Director da Alfandega de Alcantara* [1995] ECR I-3573 paras 19-21; Case C-83/94 *Leifer* [1995] ECR I-3231 paras 32-41; Case C-341/94 *Allain* [1996] ECR I-4631 para 24; Case C-29/95 *Pastoors v Belgium* [1997] ECR I-285 paras 24-26. The GPSD provides that Member states shall: "lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 15 January 2004 and shall also notify it, without delay, of any amendment affecting them." Directive 2001/95/EC, article 7: this provision was considerably extended from Directive 92/59/EEC, article 5. Regulation (EEC) No 2309/83 on the centralised authorisation procedure for medicinal products similarly provides: "each member States shall determine the penalties to be applied for the infringement of the provisions of this regulation. The penalties must be sufficient to promote compliance with those measures." The "effective, proportionate and dissuasive" test is also adopted under Council Decision 2003/80/JHA of 27 January 2003 on the protection of the environment through criminal law, OJ L 29/55, 5.2.2003.

operator or company) to make periodic checks to ensure rest periods were being observed and to take appropriate steps to prevent repetition of breaches.[568]

With the exception of the GPSD,[569] no Community-level product regulatory measures make significant stipulations as to the organisation or powers[570] of national competent authorities, or offences, sanctions or penalties for breaches.[571] The former organisational aspects are entirely left to the discretion of member states, and the latter enforcement aspects are to be imposed under the criminal law or other domestic arrangements of Member States. These matters are not subject to harmonisation and no attempt has been made to harmonise them.[572] This may give rise to considerable variation between the law in different Member States and the practice of their Courts, and is an area that would repay careful study.

Problems in standards and consistency of enforcement

The Council recognised in 1994 that there was lack of mutual confidence and transparency between administrations, and this engendered problems over the effective, efficient and uniform enforcement of Community legislation across all Member States.[573] Accordingly, the Commission put forward a policy framework for administrative co-operation between Member States' administrations and the Commission in the implementation and enforcement of Community legislation in the internal market, that incorporated guiding principles including provision of mutual assistance, exchange of information under conditions of confidentiality and proportionality, and ensuring transparency of measures, control mechanisms and their modalities of operation. The following initiatives occurred:

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568. Case C - 70/90, *Belgium v. Vandevenne and others* [1993] 3 C.M.L.R. 608.

569 See ch 11.

570 Directive 88/378/EEC on toys, article 12 contains brief powers.

571 As an example of the variations in enforcement sanctions that can occur, contravention of producer's duties 2, 3 or 4 or distributor's duty 3 under the UK General Product Safety Regulations 1994, Regulation 12, was not an offence. This is a surprising omission. The UK Government took the position that the nature of these obligations was not sufficiently prescriptive or clearly defined to be made subject to criminal penalties and that of the goals of product safety and consumer protection could be adequately achieved by use of the product-directed (as opposed to person-directed) powers contained in Part II of the Consumer Protection Act 1987, such as suspension notices, forfeiture orders, prohibition notices and notices to warn. This is a curious state of affairs but has not been the subject of objection by the Commission. It is true that the definition of these duties is general and imprecise, but no more so that the only other relevant method of quasi-enforcement by means of civil liability for negligence, which is defined in similarly wide terms as breach of a reasonable standard of conduct. The failure to provide for what might be regarded as the normal enforcement sanction by one Member State, when such a sanction exists in others, is not satisfactory.

572 The Commission's New Approach Guide states: "Each Member State can decide upon the market surveillance infrastructure, for example there is no limitation on the allocation of responsibilities between authorities on a functional or geographical basis as long as surveillance is efficient and covers the whole territory. As a result, the legal and administrative market surveillance infrastructures differ from one Member State to another. This requires, in particular, that efficient administrative cooperation between competent national authorities is in place so that an equivalent level of protection can be ensured throughout the Community..."

573. Communication from the Commission to the Council and the European Parliament on the development of administrative co-operation in the implementation and enforcement of Community legislation in the internal market COM (94) 29 final, 16.2.1994; adopted by Council resolution of 16 June 1994 on the development of administrative cooperation in the implementation and enforcement of Community legislation in the internal market. OJ No. C 179/1, 1.7.1994.

- notification by each Member State to the Commission by the end of 1994 of contact points and essential information on their administrative structures in relation to 18 areas including technical harmonisation (directives on the elimination on barriers to trade), public procurement, the general product safety directive, foodstuffs and notification of technical regulations.

- the establishment of communications systems so as to achieve information exchange, involving the establishment of common frameworks.[574] The Commission specifically noted that cooperation between two or more authorities may be necessary in order to ensure that a product found to be unsafe in one area is no longer manufactured in other area or marketed in a third.

- the adoption of a consistent approach to product testing by laboratories.[575]

- the exchange of 1900 national officials engaged in the implementation of Community internal market legislation (Karolus programme), aimed at building closer co-operation and mutual confidence between national administrations.[576] General product safety was one of the priority areas selected for 1994.

- unofficial collaboration from 1991 between national non-food enforcement officials (the Product Safety Enforcement Forum of Europe - PROSAFE), facilitated by the European Consumer Safety Association (ECOSA).

Evaluation of the current position

Recent reviews of various Directives have consistently identified ongoing problems with market surveillance and enforcement. An approach based on mutual recognition is increasingly seen as ineffective and new initiatives are occurring sometimes based on more prescriptive integration, albeit with different approaches remaining in the different sectors.

For GPSD products, the Commission has accepted that there are serious weaknesses in market surveillance,[577] and ECOSA has said bluntly that most Member States lack even a basic enforcement structure and in those that do responsibility is delegated to local authorities that lack proper co-ordination and funding.[578] The 1999 Study on the GPSD found that Member States differ in their models for national authorities, the principal models being federal (Spain and Germany, with great

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574. Council Resolution of 20 June 1994 on Coordination with regard to information exchange between administrations. OJ No. C 181/1, 2.7 94. An example of a measure taken was the Commission's call in 2000 for projects to which it might make a grant to promote administrative co-operation between national authorities responsible for market surveillance in the area of New Approach Directives, to foster exchange of best practice, strengthen practical co-operation and achieve more effective market surveillance by supporting specific market surveillance projects undertaken by at least two EU Member States: http://www.europa.eu.int/comm./emterprise/grants/sec_04.htm.

575. Provisional working document "New Approach Directives: Official Market Control" Doc. Certif 92/2, 4.3.92

576. Council Decision 92/481/EEC of 22 September 1992 on the adoption of an action plan for the exchange between Member State administrations of national officials who are engaged in the implementation of Community legislation required to achieve the internal market, OJ No. L 286/65, 1.10.92, amended by Commission Decision 94/818/EC of 16 December 1994, OJ No. L 337/89, 24.12.94.

577 *Commission Report to the European Parliament and the Council on the experience acquired in the application of Directive 92/59/EEC on general product safety*, COM(2000) 140.

578 *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001). As examples of the latter, ECOSA cites that responsibilities for market surveillance and enforcement are those of the 16 Bundeslaender in Germany and the 220-odd local authorities in the United Kingdom.

disparities between the resources of regions), decentralised (Austria, Finland, France, United Kingdom and the Netherlands) or centralised (the others), and they also differ in the extent to which competency for consumer products is held or disseminated amongst one or several ministries or authorities, and this gives rise to issues of coordination.[579] All Member States complained about lack of resources in the 1999 GPSD review,[580] leading to ineffective monitoring of the market and absence of technical expertise and laboratories. The result was an extension of Member States' obligations under the 2001 Directive with the aim of forcing greater and more resources to be given to the monitoring and enforcement of consumer product safety, and establishment of a European Product Safety Network of national authorities.[581] Industry has called for formalisation of a centralised, co-ordinated mechanism.[582] The lack of co-ordination can be illustrated by divergencies in national approaches to banning yo-yo balls after near-lethal choking of three children.[583]

Similarly, in relation to New Approach products, the Mutual Joint Visit Programme carried out between national market surveillance officials in 1999[584] concluded that there is considerable variation between Member States on the level of market surveillance:

> "Some Member States have a "proactive" approach to market surveillance, while others adopt a "reactive" strategy. A reactive strategy covers activities such as response to complaints, notifications received through the system for rapid exchange of information between surveillance authorities (RAPEX) established by the directive on ... [GPSD], safeguard clause notifications and basic customs checks. A proactive approach suggests targeted campaigns, use of risk assessment tools, special co-operation with other authorities, e.g. customs, manufacturer's associations, consumer groups or media. For some directives, some Member States do not have a well-defined strategy."[585]

Every Member State was reported to face an issue of limited resources for surveillance,[586] and the Commission suggested a rough estimate of one to three core surveillance staff to one million head of population:[587] no statistics seem available as to the ratios that apply in Member States, but the Commission noted that severe financial restrictions in some Member States negatively affected effectiveness in market surveillance, and that some do not have EMC testing facilities, which are costly. Only a small number of Member States reported any significant enforcement activity

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579 *Study on Directive 92/59/EEC*, Centre de Droit de la Consommation, Louvain-la-Neuve, 1999.

580 Ibid.

581 Directive 2001/95/EC, article 10.1. See ch 11.

582 Conclusions of various speakers at the Consumer Product Recall Conference, Stockholm, Sweden, 25-26 June 2001.

583 pressoffice@tsi.org.uk, April 2003.

584 This was funded by the Commission and involved all Member States plus Norway in five sectors (toys, electromagnetic compatibility, low voltage equipment, machinery, and personal protective equipment): *Consultation Document Prepared by the Directorate General for Enterprise on the review of the New Approach*, (European Commission, 2001), section 2.5.

585 Ibid.

586 The Commission's *Guide to the implementation of directives based on the New Approach and the Global Approach* (2000), section 8.1, states that authorities should have adequate personnel and technical resources and powers in order to be able to carry out their functions and, by implication, fulfil their Treaty obligations, providing professional integrity and guaranteeing the quality of test data, with testing facilities complying with the relevant criteria of EN 45001 standard.

587 Ibid.

(prosecutions, written warnings, product suspensions or recalls), but it was not clear whether this was because co-operation with manufacturers made such measures unnecessary.[588]

The 1999 Study on the Low Voltage Directive[589] also found that the significant differences between the national laws in their approaches to safety that had existed prior to the Directive remained, with significant differences in philosophy and approach which were not assisted by the absence of any provisions in the Directive that would assist in establishing a consistent approach to market surveillance.[590] It was said that enforcement action through the courts was often not required and that most Member States seek to obtain corrective action by agreement with the manufacturer or importer.[591]

The Commission asserted that Member States should achieve a common level of market surveillance activity for New Approach products, based on specified criteria[592] and noted that some Administrative Co-operation Groups of Member States' market surveillance experts meet informally but only under some New Approach Directives.[593] It stated that there is considerable potential for Member States to make efficient use of resources by sharing the burden of control campaigns and tests, and to divide surveillance activities by product type.[594] Further, it stated that the lack of appropriate resources and technical expertise to process and analyse safeguard clause notifications is a major problem, and called for a mechanism permitting the Commission to adopt a Decision if another Member State objects to the initial notification.[595]

Enforcement policy

The importance of a sufficiently robust and effective enforcement policy is clear from the safety perspective. The United Kingdom's National Audit Office considers that "rigorous inspections have contributed to the high quality of authorised medicines".[596] The inspection function of the

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588 Ibid.

589 A H Palmer, *Study on the Implementation of the Low Voltage Directive* (European Commission, 1999).

590 Ibid, sections 5.5.10, 7.1, 7.5.

591 Ibid, section 7.5.

592 *Consultation Document, supra*, section 2.5.2.

593 For low voltage, EMC, machinery, personal protective equipment, recreational craft, lifts, and radio equipment and telecommunications equipment.

594 *Consultation Document, supra*, section 2.5.3.

595 Ibid, section 2.5.4. The ability to resolve differences of view swiftly, definitively through a binding decision, and on the basis of the best scientific and technical support proved to be essential within the medicinal product sector during the evolution of the mutual recognition system in the 1990s.

596 National Audit Office, *Safety, quality, efficacy: regulating medicines in the UK*, (The Stationery Office, 2003). The following information was provided to the author in letters in 1999: the Medicines Control Agency "undertakes over 400 criminal investigations every year into allegations that medicines legislation has been breached. On average 50 prosecutions are brought, including cases which are serious or where other measures may not have succeeded. The success rate [consistently exceeds] 90%. Other cases are resolved by formal cautions, warnings or advice apart from a small number of cases in which either the allegations are unfounded or the case is more appropriate to another enforcement agency." In 2001/2002, the MCA seized and removed from the market around 103,830 unlicensed medicinal products, and undertook 325 and 265 scheduled inspections of manufacturing and wholesaling sites respectively, of which 54 were

Medicines Control Agency complies with quality standard ISO 9002. The MCA has performance targets of inspecting all UK manufacturing sites every two years and overseas sites every three years.[597] It analyses 3,000 test samples a year. On the other hand, the prevailing policy towards enforcement in the United Kingdom throughout the 1990s at least has been that of "light touch",[598] in other words encouraging compliance and product safety primarily through advice and assistance, and reserving the sanction of prosecution for instances where Such a policy has the advantage of saving cost for both enforcers and commercial entities.

As noted above, Member States differ as to whether their enforcement policies under New Approach legislation are proactive or reactive/passive.[599] The Commission's 1999 study on the 1992 GPSD[600] found that while the powers available to member states under national legislation were on the whole extremely similar to those stated in the Directive, use of the powers varied considerably in practice, with some states almost never using them and considering voluntary measures adopted by professionals to be satisfactory (Greece, Ireland, Luxembourg, Austria, Germany) whereas only a minority of states regularly use their powers or sanctions (France, the Netherlands, Belgium, sometimes the United Kingdom[601]).[602]

The Commission considers that market surveillance should be carried out in accordance with the principle of proportionality, so that, for example, action must be in accordance with the degree of risk or non-compliance and the impact on the free circulation of products may not be more than is necessary for achieving the objectives of market surveillance.[603] Implementation of this principle would require that authorities maintain statistics and undertake risk assessment procedures that identify those products that pose higher risks or non-compliance: there is no Community obligation

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overseas and eleven on behalf of the EMEA, plus re-inspections and unannounced inspections: Medicines Control Agency, *Annual Report and Accounts 2001/02* (The Stationery Office, 2002).

597 Ibid.

598 For a detailed study of UK enforcement practice and the inter-relation between consumers, enforcement agencies and business, see R Cranston, *Regulating Business: Law and Consumer Agencies* (The Macmillan Press Ltd, 1979). See also the fact that under the Low Voltage Directive authorities seek to obtain corrective action voluntarily and enforcement action through the courts is often not required: A H Palmer, *Study on the Implementation of the Low Voltage Directive*, (European Commission, 1999), section 7.5.

599 *Consultation Document, supra.*

600 *Study on the practical application of Directive 92/59/EEC on General Product Safety*, Centre de Droit de la Consommation, Louvain-la-Neuve, 1999.

601 Some Member States have useful precedents which could be built on, such as *Working with Business: a Code for Enforcement Agencies* (Department of Trade and Industry, 1993); *Enforcement Concordat* (Department of Trade and Industry, 1998), which promulgated Principles of Good Enforcement comprising policy (standards, openness, helpfulness, complaints about service, proportionality, consistency) and procedural aspects.

602 Case C-365/97 *Commission v Italy* [1999] ECR I-7773 held that the powers of the Commission in the enforcement of Directives are not limited to ensuring their proper implementation but extend to the supervision of certain individual cases of non-compliance, and it can bring Article 226 actions against a member state (for failure to fulfil its obligations) based on breach of general rather than specific obligations imposed by a Directive. This case was based on failure by Italy to adopt measures to ensure that waste was disposed of without endangering human health and without harming the environment under Directives 75/442/EEC and 91/156/EEC.

603 *Guide, supra*, para 8.1.

on Member States to do this, and Member States seem to vary in their practice on keeping (and publishing) such statistics.

Notified bodies

The Commission has stated that, as a general rule, it is inappropriate for notified bodies to be responsible for market surveillance, and that the functions of conformity assessment and market surveillance must be distinguished in order to avoid conflicts of interest.[604] Nevertheless, it is difficult to see how notified bodies could carry out their approval and auditing functions if they are not informed of safety issues as they arise, whether by competent authorities or manufacturers, and there is therefore a strong argument for including this as a regulatory obligation, particularly since a number of contracts between notified bodies and manufacturers explicitly provide for this and some competent authorities pass on the information in practice.[605]

CONCLUSIONS

Powers and mechanisms

Once again, the picture is that the mechanisms that might be expected to be included in the legislation vary significantly between different product regimes, and there are some curious gaps and seemingly little justification. An obvious example is the absence of powers for authorities to check that manufacturers are complying with pre-marketing obligations (implying powers of inspection, search, testing of products). Other important gaps are the absence of unified enforcement policies, and the absence of a power to suspend or withdraw a centrally-authorised medicine.

The GPSD contains the most extensive legal provisions, and specifies that Member States shall have particular market surveillance resources and reasonably comprehensive powers. Few of these provisions are found in any other system, save that the Pharmacovigilance System and, to a lesser extent, the medical device vigilance system, are extensive and sophisticated, although they are based significantly on guidelines rather than legal provisions, possibly for reasons of enabling them to evolve quickly and flexibly.

The focus of the GPSD on post-marketing provisions has only been significantly extended as from 2004. A reason for the failure of the New Approach, cosmetics and biocides systems to focus on

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604 *Guide, supra*, para 8.1.

605 See standard terms and conditions of BSI Limited, Underwriters Laboratories Limited, and others.

post-marketing surveillance and vigilance mechanisms lies with the Community's treaty preoccupations with *access* of products to the market, rather than with safety issues *per se*. The pharmacovigilance provisions can be explained by recognition that ensuring the safety of medicinal products is a permanent process, and it is the ultimate responsibility of the authorities, rather than manufacturers or distributors. Yet, evidence from studies of the GPSD that prompted the 2004 extensions was justified on the basis of failure of Member States to construct appropriate national or collaborative surveillance mechanisms – not that the number of unsafe products was at an unacceptable level (virtually no statistics were produced on this issue).[606] The driver was, therefore, an issue of European integration, rather than an absence of safety.

Academic insights on enforcement

Academic analysis has concluded that enforcement plays an essential role in regulation, and both the design of enforcement mechanisms, their policies and practical operation are crucial for the effectiveness and success of the system.[607] The ideal of a "responsive" approach has been suggested, comprising hierarchies of sanctions and of regulatory strategies in pyramidal structures,[608] which combines a synergistic approach between compliance and deterrence,[609] punishment[610] and persuasion. Different strategies, and different regulates, call for different kinds of rule: considerations of fairness and human rights demand that prosecutions should be based on precise rules, whereas promotion of good practice may involve less precise rules and more generalised principles.[611]

Baldwin has convincingly stressed, first, that rules do not produce compliance when those willing to comply do not know what compliance involves, or when those less willing or able to comply are not informed or stimulated in the appropriate manner, and, secondly, that effective rule-use demands that those who design rules take into account the enforcement strategies that will have to be used to

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606 *Commission report to the European Parliament and the Council on the experience acquired in the application of Directive 92/59/EEC on general product safety*, COM (2000) 140 final.

607 R Baldwin and M Cave, *Understanding Enforcement*, (Oxford, 1999), ch 8; R Cranston, *Regulating Business* (London, 1979). See also P Selznick, op cit.; and E Bardach and R Kagan, *Going by the Book – The Problem of Regulatory Unreasonableness* (Temple UP, 1982), ch 5.

608 I Ayres and J Braithwaite, *Responsive Regulation* (Oxford, 1992), 25, who favour the "benign big gun" approach (agencies that speak softly but carry a big stick) coupled with the minimal sufficiency principle (the less salient and powerful the control technique used to secure compliance, the more likely that internalisation will result, leading to the following integrated approach: 'Effective regulation is about finesse in manipulating the salience of sanctions and the attribution of responsibility so that regulatory goals are maximally internalised, and so that deterrence and incapacitation works when internalisation fails'.

609 A Reiss, 'Selecting Strategies of Social Control over Organisational Life', in K Hawkins and J Thomas (eds), *Enforcing Regulation* (Boston, 1984). For a detailed study of UK enforcement practice and the inter-relation between consumers, enforcement agencies and business, see R Cranston, *Regulating Business: Law and Consumer Agencies* (The Macmillan Press Ltd, 1979).

610 For claimed advantages of the tough approach, see E Bardach and R Kagan, *Going by the Book – The Problem of Regulatory Unreasonableness* (Temple UP, 1982).

611 R Baldwin, op cit.

achieve compliance.[612] He suggests that organizational divisions and arrangements that encourage the pursuit of group rather than organizational ends should be avoided.[613]

In answer to quantitative issues, economic theory shows that aiming for perfect compliance or complete elimination of hazard is not rational, since enforcement costs will rise to an extent that does not justify the incremental increase in enforcement or safety.[614] This points to the policy of achieving the socially optimal level of enforcement, where the extra costs exceed the resulting benefits,[615] but in relation to safety this still involves value judgments over what balance is acceptable.

Shrader-Frechette has also argued that risk assessors tend to err on the side of avoiding Type I errors (rejection of the null hypothesis, that there is no harmful effect, that turns out to be false), whereas would be preferable to avoid Type II errors (acceptance of a null hypothesis that turns out to be false).[616] This has implications for the burden of risk, and argues for protecting consumers rather than permitting producers to sell goods, and for the precautionary principle, but the approach is subject to a number of objections.[617]

A confused and fragmented situation

Clearly there is a bewildering maze of unharmonized and possibly conflicting national offences, enforcement powers, authorities, policies, resources, and decisions. The reasons why these aspects are not harmonized are concerned with the continuing absence of suitable powers in the Treaty, and can be attributed to the sensitivity of the political relationships between the Community institutions and the Member States. This sensitivity is expressed in the principle of subsidiarity, under which the Community refrains from interfering too far in the internal order of Member States. A further significant factor is that Community harmonisation has hitherto not sought to address differences in the member states' legal systems, which would have the consequence of opening up the field of enforcement law to harmonisation. However, the first steps towards harmonisation of legal systems and rules are now being taken.[618]

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612 R Baldwin, *Rules and Government* (Oxford, 1995), p 173.

613 Ibid.

614 S Breyer, *Breaking the Vicious Circle* (Cambridge, Mass., 1993), 10-13; S Meyers, 'Applications of *De Minimis*', in C Whipple (ed), *De Minimis Risk* (1987), 102.

615 Amongst various sources see S Shavell, 'The Optimal Structure of Law Enforcement' (1993) *Journal of Law and Economics* 270-287.

616 K S Shrader-Frechette, 'Uncertainty and the Producer Strategy: The Case for Minimising Type II Errors in Rational Risk Evaluation', in *Risk and Rationality* (Berkeley, 1991), ch 9.

617 Summarised in R Baldwin and M Cave, op cit, ch 8.

618 Article K.1(b) of the EU Treaty of 1992 established that a matter of common interest was judicial cooperation in civil matters; Green Paper on European Contract Law, COM (2001) 398, 1.7.2001; O Lando and H Beale (eds), *Principles of European Contract Law* (Kluwer, 2000).

It is difficult to see what rationale there could be for the continuation of differences in enforcement powers and sanctions in a situation where the other related regulatory provisions have been harmonised. Limited mechanisms for consistency do exist, such as the developing approaches towards education for officials and exchange of information between authorities. For as long as national authorities remain with significant roles in market surveillance and enforcement, there will be scope for mechanisms to be introduced that encourage consistency and quality[619] in the same way as apply to other (i.e. commercial) operators whose activities affect product safety, such as training, best practice guidelines,[620] and independent and peer auditing.

The development from the informal PROSAFE to the formal Product Safety Network is to be taken for consumer products that do not fall within the vertical systems. It remains to be seen whether the experience of the Pharmacovigilance System will be applied in this wider context: the continuation of a proliferation of national enforcement authorities and the absence of an integrated communication and coordination mechanism are failings, and can be expected to lead to both inefficiencies in communication and also duplicative and inconsistent decisions across the Community in relation to the same product safety issues.

The opportunity has also not been taken to integrate product safety mechanisms further by including within the same system several families of vertically-regulated products, as well as use of the same products in workplace environments. The current approach is fragmented in that it involves collaboration solely under individual Directives, involving officials at both Commission and national levels who are within separate teams or ministries, and the questions that arise are not only whether the existing lack of overall coordination can be improved by existing means,[621] but also whether a more economic and effective approach would be for systems to be integrated within a single overarching framework: this does not seem to have been addressed.

Overall, there is very considerable force in the argument for the establishment of an integrated European Product Safety Agency,[622] on the American model,[623] with separate but connected divisions

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619 An organisation in which senior governmental officials involved in safety regulation has called for an integrated injury data collection system with all reports being thoroughly investigated: *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001).

620 There can be an unhelpful tendency to use enforcement outcomes (i.e. numbers of prosecutions) as a measure of quality in surveillance and enforcement, when the real measures relate to numbers and percentages of safe and unsafe products.

621 ECOSA called in *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001) for stronger collaboration in addressing a European consumer safety policy that covers the five essential components of injury monitoring, research for effective action, consumer protection regulation (eradicating differences in transposition) and standards, (the example of an absence of standards for cigarette lighters, in view of the need to make them child-resistant), better enforcement and market surveillance, and safety promotion.

622 The Commission has postulated the increased use of agencies in executive tasks but not for adopting regulatory measures, or arbitrating between conflicting public interests, exercising political discretion or carrying out complex economic assessments: *European Governance: A White Paper* Com (2001) 428, 25.7.2001.

dealing with specific product sectors. It is possible to justify integrated surveillance mechanisms on grounds of cost-efficiency, particularly in relation to the use of powerful databases[624] and expert assessments, of speed of identification of hazards, and of the consistency and speed of responsive action. These considerations raise the issue not just of improved co-ordination mechanisms between Member States and the Commission, which the evidence supports,[625] but also of whether the system that would be most efficient and would make the best contribution towards the achievement of safety would be for one, or more, European Product Safety Agencies.[626]

It is difficult to avoid the impression that post-market surveillance in the Community is in a rudimentary state[627] and that collaborative mechanisms that could be anticipated to improve public safety are not currently in place for any product sectors other than medicinal products and perhaps medical devices. From the points of view of both removing barriers to trade and also encouraging product safety, harmonization of enforcement issues is one of the most important unresolved topics for the Community.

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623 The system for post-market surveillance for consumer products in USA places reliance on a single Federal agency, the Consumer Product Safety Commission, rather than 50 state agencies, in order to maximise efficiency, speed and authority existing from a centralised database and enforcement powers. There are similar US centralised agencies dealing with food, medicines, medical devices and diagnostics (the Food and Drugs Administration) and motor vehicles (National Highway Transportation Safety Administration), and the Bureau of Alcohol, Tobacco and Firearms.

624 Establishment of data collection systems for injuries was recommended in Recommendation of the Council Concerning the Establishment of Data Collection Systems Related to Injuries Involving Consumer Products, OECD, C(77)139.

625 The absence of communication arrangements between authorities can clearly have an adverse impact on safety. For example, by March 1998 the United Kingdom had informed the Commission that it had issued suspension notices in respect of 17 types of toys but the Commission had not notified any other member states because of the absence of a formal vigilance system: Personal communication with officials at the Department of Trade and Industry.

626 The European Parliament supports creation of further independent regulatory authorities within the framework described in the White Paper if specific scientific or technical expertise is required and a decentralised administration seems appropriate, but this must not lead to a reduction in expert and judicial scrutiny by the Commission or to any watering down of the Commission's political accountability: European Parliament Report on the Commission White Paper on European governance, 15 November 2001, para 16.

627 This has also been found to be the case in relation to consumer protection generally, where the Commission has identified a need for "significant improvement" in the way laws are enforced and proposed to establish a network of enforcement authorities in each member State linked in a mutual assistance mechanism through reciprocal rights and obligations: Proposal for a Regulation of the European Parliament and of the Council on cooperation between national authorities responsible for the enforcement of consumer protection laws, COM(2003) 443, 18.7.2003.

13. CONTROL OF DISTRIBUTION

Rationale

The purpose of controlling distribution is to ensure that the product which reaches the hands of the consumer does so in the condition intended by the manufacturer, and the state in which it left him.

GPS duty for consumer products

The GPSD provides an obligation on distributors[628] of consumer products as follows:

> "to act with due care in order to help to ensure compliance with the general safety requirement, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with this requirement. In particular, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks *keeping and providing the documentation necessary for tracing the origin of products,* and co-operating in the action taken *by producers and competent authorities* to avoid these risks. *Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently*".[629]

These obligations are generalised and unspecific. It is unclear what a distributor has in practice to do in order to satisfy this duty. It is arguable that a duty to act with due care, which is familiar as a concept under the common law of negligence, is distinct from a duty to ensure compliance with the general requirement only to place safe products on the market. It is even arguable that these two duties are different in form, since the former is fault based whereas the latter appears strict.

The general GPS duty is seemingly subject to a subjectivity qualification: the phrase "within the limits of their respective activities" is clearly intended to differentiate between distributors depending on the scope of the *normal* activities of each and also their resources.[630] Thus, guidance by the Department of Trade and Industry suggests that a retailer with multiple outlets will be subject to higher standards than a corner shop.[631] This may be a pragmatic approach but is difficult to reconcile with the consumer protection goal.

In any event, the generalised obligation to act with due care is clarified by reference to two explicit

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628 The definition of a distributor for the purposes of Directive 2001/95/EC is restricted to any professional in the supply chain whose activity does not affect the safety properties of a product, whereas any such professional whose activities may affect the safety properties of a product is subject to the more onerous obligations that apply to producers: article 2 (e) and (f). The obligations on producers are analysed at ch 8..

629 Directive 2001/95/EC, article 5.2: the wording added to Directive 92/59/EEC, article 3.3 is in italics.

630 See discussion in C Hodges et al, *Product Safety* (1996), pages 138-141.

631 Department of Trade and Industry, *The General Product Safety Regulations 1994: Guidance for Businesses, Consumers and Enforcement Authorities* (1995).

duties:

(a) not to supply a dangerous product, or one which he should have presumed to be dangerous; and

(b) to participate in monitoring, to pass on safety information and to cooperate in action taken to avoid risks.

The first of these duties applies pre-marketing and the second post-marketing: they are similar to the obligations on producers discussed above. It is not a requirement that distributors of consumer products should have to operate a quality system or otherwise be subject to a standard of good distribution practice but adoption of such measures would undoubtedly assist.

Medicinal products

With the exception of medicinal products, sector-specific Directives do not cover the activities of distributors. The pharmaceutical provisions are more precise than the GPSD principles, and are supplemented by guidelines. Directive 92/25/EEC on the wholesale distribution of medicinal products requires persons engaged in such activity to hold an authorisation granted by a competent authority, and be subject to checks on their persons and establishments and inspection of premises.[632] Amongst its obligations, it requires them to[633]

- keep records of products received or dispatched, dates, quantities, and names and addresses of suppliers and consignees;
- have an emergency plan which ensures effective implementation of any recall from the market;
- comply with the principles and guidelines of good distribution practice for medicinal products (GDP) published by the Commission.[634]

Even that Directive, however, does not impose the general GPS obligation to act with due care or positively to take action, such as by notifying persons up or down the chain of distribution (especially manufacturers, doctors and patients) or the authorities, or by instituting a recall.

Good Distribution Practice (GDP)

The Commission's GDP Guidelines state that the pharmaceutical industry operates to a high level of quality assurance and that this policy ensures that products released for distribution are of the appropriate quality. They then state what is in effect the purpose of controlling distribution, which

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632 Directive 92/25/EEC, Art. 3.

633 Ibid, Art. 6(a), (e) and (f).

634 See European Commission, *Guidelines on Good Distribution Practice of Medicinal Products for Human Use* 94/C 63/03, OJ C 63/4, 1.3.94.

is that this level of quality should be maintained throughout the distribution network, so that products which are distributed to pharmacies and other sale outlets without any alteration in their properties. The rules are based on underlying concepts of quality management and quality systems as described in the harmonised standards EN 29000 series. The specific principles applicable to medicinal products are

then stated as:

> "The quality system operated by distributors (wholesalers) of medicinal products should ensure that medicinal products that they distribute are authorised in accordance with Community legislation, that storage conditions are observed at all times, including during transportation, that contamination from or of other products is avoided, that an adequate turnover of the stored medicinal products takes place and that products are stored in appropriately safe and secure areas. In addition to this, the quality system should ensure that the right products are delivered to the right addressee within a satisfactory time period. A tracing system should enable any faulty product to be found and there should be an effective recall procedure."

More detailed provisions are specified covering:

- *personnel*: an appropriately qualified management representative should be appointed in each distribution point who should have defined authority and responsibility for ensuring that a quality system is implemented and maintained. Other key personnel should have appropriate ability, experience and training.
- *documentation:* requirements for orders, procedures and records.
- *premises and equipment:* requirements for receipt and storage, including protection of goods from damage, contamination and temperature extremes, stock rotation.
- *deliveries to customers:* delivery only to authorised personnel, traceable documentation and security.
- *returns:* maintenance of control and security over non-defective returns; emergency plan and recalls[635]; isolation of counterfeits;
- *self-inspections*;
- *provision of information of request to competent authorities.*

Other aspects covered under GDP are interference or adulteration by a third party, shelf life, conditions of storage (especially temperature and humidity), EMC interference, maintenance of sterility. Many aspects are specified on manufacturers' labels.

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635 see ch 11.

Conclusions

If the justifications for imposition of regulation on distributors is that it should apply in the case of products for which performance and/or safety are critical and may be affected by the conditions in which they are stored or transported, there may be a case for extending regulation to products such as sterile or active implantable medical devices and certain types of mechanical, measuring, testing or diagnosis equipment. It may be argued that sterility or other safety aspects can be adequately protected by appropriate packaging (but this is not a pre-marketing requirement) and by labelling (such as by referring to the sterile state and the shelf life, which are requirements).

An obvious lacuna is that although the GPS duties apply to consumer products no similar provisions apply for non-consumer products. There is no reason why controls should not cover all activities within the delivery chain: Some products can only be used after an assembly, installation, calibration or other manipulation has been carried out. For this reason, some directives require that a product conforms with the essential requirements when it is put into service, rather than (or in addition to) when it is placed on the market. Similarly, for lifts and pressure equipment the assembler is considered to be the manufacturer.

14. RESPONSIBILITIES ON USERS

The purpose of responsibilities on users

Controls exist on virtually all commercial actors in the distribution chain, but not systematically on users. On one view, this might be irrational, in that the objective is to ensure safe use, and the evidence is that accidents are predominantly caused by incorrect use of products.[636] Causing an accident to oneself will mean that compensation is not claimable from the producer or supplier absent a product defect or negligence, so the economic risk is allocated to the user although, in the regulatory context, manufacturers are sometimes required to take into account known or foreseeable risks when designing or labelling their products.[637] It is only where users may harm others that regulatory law imposes regulatory controls, such as licensing for drivers of motor vehicles.

Putting into service

Some New Approach Directives do impose obligations on the person who "puts them into service", although this may be a commercial operator.

Restrictions on use

The use of some products is restricted to particular users, or is constrained by approval and/or supervision by particular individuals. An example of user restriction is the requirement for motor vehicles to be driven on public roads by holders of licences granted by a competent authority, often dependent on both satisfaction of both objective criteria (age, absence of disability, passing a written examination) and subjective criteria (assessment of performance in operating the product). These rules are, however, national and unharmonized, even if largely with standard features.

An example of constraint on product availability is the classification of medicines as those subject to medical prescription or not, which has consequences not only as to direct availability to consumers but also an absolute ban on advertising prescription medicines to the general public.[638] The classification criteria are based on whether the product is likely to present a danger (how much of a danger is a moot issue) when used correctly or incorrectly.[639]

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636 See Appendix 2 et seq. It has been reported that 70% of the tyres fitted on European cars are in poor condition as a result of insufficient pressure: European Tyre and Rim Technical Organisation, 2001.

637 See ch 11 and Table 5and ch 19.

638 Directive 92/2/EEC, article 3.1.

639 Directive 92/26/EEC: see ch 4.

Obligations on users

Directive 98/8/EC requires Member States to impose an obligation on users to use biocidal products properly, including in compliance with their authorised conditions and specified labelling provisions, as well as in minimum quantities required for rational use.[640] It has been seen above that information provided by users can be critical to post-marketing vigilance systems, but there is no requirement to notify such information.

The absence of provisions prohibiting re-use of single use medical devices has been criticised.[641] The Economic and Social Committee has commented that children are at particular risk from consumer products and there is an obligation on parents to be aware of their responsibilities.[642]

Servicing

One possible approach to on-going safety would be to require users to have products periodically inspected or serviced, or to require manufacturers to do this for their products. This approach would clearly be both impracticable and hugely expensive for nearly all consumer products: the risk benefit balance would be satisfied, as long as products remain relatively safe.

Products such as automotive machines do require periodic servicing. Certain Directives deal with this by imposing obligations on the manufacturer to provide *information* with the product when it is placed on the market, so that the customer can ensure that proper servicing is undertaken, as, for example, under the essential requirements on labelling for medical devices:

> "all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times."[643]

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640 Directive 98/8/EC, article 3.7.

641 C Hodges, 'The Reuse of Medical Devices', *Medical Law Review*, 8, Summer 2000, 157-181.

642 Opinion of the Economic and Social Committee on "General Product Safety", 2000/C 51/16, DJ No C51/67, 23.2.2000, para 2.3.3.

643 Directive 93/42/EEC, Annex I, section 13.6(d).

15. CONCLUSIONS ON SAFETY MECHANISMS

Part Two has critically analysed the various mechanisms included in the sectoral and horizontal legislation that contribute to the achievement of the safety in use of products. Various gaps and inconsistencies have been found in the mechanisms that are adopted in the various individual regimes, but this is not surprising given that the sectoral regimes, with the exception of the New Approach family, have developed independently and at different times. It can be seen that each individual mechanism is intended to contribute to product safety, and is likely to do so. The extent of such contribution, however, could only be measured empirically.

Although the comparisons carried out in the above analysis have inevitably led to conclusions that some product regimes contain greater controls than others, it does not necessarily follow that every system should be identical or should comprise a complete range of regulatory mechanisms. This is because it is clear that different products present varying levels of risks and it is therefore proportionate to treat them individually as regards the level of safety controls that are appropriate. Proportionality is the key concept, not only in relation to degrees of risk but fundamentally because otherwise the cost of simple, low-risk products would be prohibitive.

Every safety mechanism that is used is based on the exploitation of *knowledge* and use of rational thought. This can be seen in the need for manufacturers to assemble information on their products before marketing them, and to continue the process of reassessment of safety information after marketing in the light of new information that becomes available. This process could, however, be strengthened if there were an universal obligation on manufacturers to carry out a risk assessment and to keep it up-to-date in the light of subsequent information. There is an explicit requirement for risk assessment of individual biocide products and it is implicit for medicines and some New Approach and under the extended GPSD, but this point could be clarified. The utility of carrying out a risk assessment has gained recognition in industry in recent years and if an express obligation were to become universal this would help direct all manufacturers' minds to the importance of concluding that all risks associated with their products have been considered and found to be acceptable. The existence of a formal pre-marketing risk assessment assists in the re-evaluation of any information which subsequently comes to light. Evaluation of new and unexpected information after marketing can be difficult since it has to be done "blind", without the benefit of a wide matrix of safety information that helps to put individual aspects into perspective. However, the efficiency of individual systems is only as effective as the mental capacity and memory of its operators.

Two fundamentally different approaches have been found over who has the responsibility for deciding on safety issues. The ultimate guardians of safety for medicines and biocides are the competent authorities, and the obligations on commercial operators are subsidiary even though they may be extensive. Conversely, the primary responsibility for making decisions on the safety of New Approach and general consumer products rests with those commercial entities that are responsible for marketing them, and the authorities have no role before marketing and a reactive market surveillance role in the post-marketing phase. The position for cosmetics and tobacco is something of a hybrid, with manufacturers taking specific decisions but based on prior approval of ingredients by authorities, and with some form of ongoing monitoring by authorities.

The essence of pre-marketing controls is the application of a *process*. This is recognised, for example, in the New Approach's conformity assessment process, which involves the systematic assembly of information on the design and production of the product and verification that everything is acceptable. The process is sometimes complex and involves multiple actors, such as in the case of cosmetics, biocides, tobacco and medicines. In these cases, responsibilities are shared between manufacturers, regulators (for example in publishing lists of approved substances), experts acting in committees, and even the general scientific and technical community through publication of data which is relied on by others. A further example of multiple responsibilities involves notified bodies under the New Approach system, who have an inherent conflict in exercising limited delegated regulatory powers over commercial entities but at the same time needing to act commercially in retaining their customers.

The examination of the post-marketing obligations has found that there is a strong need for integration. First, national surveillance and enforcement systems are fragmented by being left unharmonised at national level. The experience of the Pharmacovigilance System demonstrates that post-marketing systems need to be able to operate speedily, with unified and not duplicated (let alone multiple) lines of communication, with expert input, with a single decision-making point, and with consistent application of surveillance and enforcement authority. A picture of considerable confusion can be painted in this situation arising out of the new GPSD obligation to notify the authorities of dangerous products. There is the spectre of multiple notifications from many retailers and distributors of the same product being given to multiple local surveillance officials across many Member States, followed by multiple and inconsistent consequences, such as requests for further information or precipitate action. A single, ill-informed enforcement official in one State could demand recall of a safe product that causes considerable damage to consumers who use it and to

those who sell it across the Community. Would the political principle of subsidiarity survive pressure from product safety scandals or such inefficiency?

Secondly, the various product regimes exist largely in isolation, and although each can operate reasonably satisfactorily on its own, there is limited evidence of adoption of best practice from other regimes. To take an extreme example, those involved in the simple regulatory regime that applies to toys are unfamiliar with useful experience from the world of medicines. The consequence is that the availability of the vast Community market offers an opportunity to build an efficient, integrated product regulatory system in which post-marketing mechanisms operate to identify safety issues swiftly and effective, proportionate action can quickly be taken to protect consumers across the entire Community and beyond.

Thirdly, the GPSD has usefully set out broad principles of post-marketing obligations that should apply to producers, distributors and authorities. There is uncertainty over the extent to which these apply to all other product sectors. Yet there is no reason in principle why the broad principles should not apply to either all consumer products (which is unclear as a matter of law in some cases) or workplace products (which is not currently the position as a matter of law). However, the broad principles leave matters of detail to be clarified and this should be done, possibly in guidelines that apply on a sectoral basis. There is a strong proportionality argument that manufacturers of low-risk products should not be required to have as extensive vigilance systems as manufacturers of high-risk products, and the details of this need to be worked out in practice rather than as matters of law.

Distribution is an area that has received little legal regulatory attention. Controls exist for medicines, supplemented by guidelines, and generalised obligations have recently been introduced for general consumer products, but would benefit from expansion in guidelines. Attention could be given to whether the safety of particular product types requires further regulation of the conditions of distribution. Maintenance of the sterility of certain medical devices or the condition of food ingredients or the sensitivity of measuring machines may be examples.

PART THREE: THEORETICAL ISSUES AND CONCLUSIONS

16. INTRODUCTION

Part Three turns from examining the mechanisms that are adopted within the legislation to examining the legislation from different, wider perspectives. First, what follows from the fact that the nature of this legislation is *regulation*? Considerable academic analysis has developed in recent years on the theory and nature of regulation, and although much of this is directed towards regulation of the economic aspects of markets, which is not the focus of this thesis, important insights can be drawn in relation to the social aspects of regulation, which concerns the achievement of safety, and is the focus of this thesis. What is known about the nature and purposes of regulation and how it works? What points should be looked for in evaluating product safety regulation? Chapter 17 considers these points. One argument is that the impact of product safety regulation is significantly smaller than is widely believed. However, it is difficult to establish whether this is true, or to measure the exact impact of such regulation, in the absence of empirical data. A major issue will be how the legal system seeks to reconcile multiple competing socio-political values on safety issues: transparency, accountability and forums for debate are identified as important features for a successful system.

Secondly, it follows from the recognition that the analysis involves socio-political issues, that it is necessary to analyse product safety regulation in relation to the way in which the various Community actors (notably, as found in Parts One and Two, the Commission, Member State authorities, committees, European and national agencies, manufacturers, consumers) inter-relate in reaching judgments on safety regulation. What is the nature of the roles of these actors and how do they inter-relate? What tensions should be expected? In chapter 18, we examine these issues, with the aid of existing research, which is mainly socio-political in nature. Lastly, on the basis of everything that has gone before, it is possible to address the central questions posed at the outset.

This thesis is an examination of the nature and effectiveness of Community regulation on product safety. The central questions are as follows. First, to what extent does the legislation specify that products must be safe: what are the specific legal tests? Parts One and Two found that the socio-political purpose of the legislation is "safety" but that different sectors currently adopt widely differing legal tests of safety. Further analysis finds that the tests are largely incoherent, both individually and collectively. Secondly, what do we mean by "safety"? It will be seen that it is a concept that is widely misunderstood, being intrinsically variable and subjective. To the extent that it is used in legislation, it provides a socio-political policy goal, but is of little use as a legal test in

individual regulatory situations. In order to be more specific about the *level* of safety that is desired or achieved, concepts of *risk* are used. Risk is a concept based on quantification, and it is therefore necessary for there to be mechanisms that produce quantified data. Further, it is necessary to make a judgment on what level of safety/risk is acceptable in particular situations, and thus on whether it is present in any given situation. Thirdly, it will be suggested that institutional mechanisms do not currently exist that deliver sufficient quantified data on the prevailing levels of safety/risk of products or product regulatory mechanisms, so no empirical judgment can be made on whether the prevailing level of safety or the regulatory mechanisms are adequate.

However, despite the inability to carry out an empirical judgment on the success or efficiency of the regulatory system, key to its value rests on the finding that society can function on a basis of incommensurability, which can accommodate the existence of different values in relation to the acceptability of safety and risk provided there is transparency, accountability and opportunity for debate. Fourthly, therefore, the system is evaluated against the criteria of transparency, accountability and opportunity for debate.

In conclusion, these findings provide the basis for various recommendations as to the way forward.

17. THEORETICAL ASPECTS OF REGULATION

Considerable recent academic analysis[644] exists on the theory of regulation in relation to markets and the interests, roles and interaction of the main actors, namely governments, regulators, industry and consumers.[645] These analyses have largely concentrated on the economic, political and sociological aspects of regulation in general and in some particular markets.[646] Indeed, regulation is well understood as an instrument of economic and industrial policy, acting especially through the mechanism of ensuring a competitive market.[647]

The present study, however, is concerned with the issue of whether regulation promotes safety.[648] Certain concepts from existing regulation theory can helpfully be adopted in the analysis of safety issues: what follows is not a summary or critique of theoretical writing on regulation but a selective overview of certain aspects that illuminate safety regulation. The point that immediately arises, however, is how a regulatory system designed and justified on market principles, involving the economic goal of maximisation of profitability that applies in a capitalist system, can be reconciled in theory, and co-exist in practice, with the social goal of protection of safety. What mechanisms apply and what are their goals and effects? How do they inter-relate, and do they conflict or harmonize?

Some pointers from general theories of regulation

The classic justification for governmental intervention in the economic system is to remedy the inability of the mechanisms of the market[649] to deal with certain problems, such as anti-competitive behaviour or failure(s) in adequate consumer protection.[650] There is a supposed antipathy between, on the one hand, the interests of private economic operators, whose motivation is the pursuit of profit, and, on the other hand, consumers, whose interests lie in quality, price, safety and choice. There is also a generalised "public interest",[651] that may address monopoly power, particularly over

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644 B Fischhoff, S Lichtenstein, P Slovic, S L Derby and R L Keeney, *Acceptable Risk* (Cambridge, 1981) concluded that the decision-making tools then available were inadequate for the challenges that many hazards pose, and called for extensive research into theoretical, behavioural, economic and other aspects.

645 For summaries see A I Ogus, *Regulation* (Clarendon, Oxford, 1994); R Baldwin, *Rules and Government* (Clarendon, Oxford, 1995); R Baldwin, C Scott and C Hood, *A Reader on Regulation* (Oxford, 1998), who also question whether regulation is at crisis-point and needs a radical rethink; R Baldwin and M Cave, *Understanding Regulation* (Oxford, 1999); J Abraham and G Lewis, *Regulating Medicines in Europe*, Routledge, 2000.

646 See Abraham and G Lewis, *supra*; L Hancher, *Regulating for Competition: Government, Law, and the Pharmaceutical Industry in the United Kingdom and France*, (Oxford, 1990).

647 L Hancher, supra.

648 Given that modern regulation has been developing over some forty years and expressly quotes the promotion of safety as one of its aims, it is curious that such an analysis has not been undertaken before.

649 Ogus, op cit, distinguishes the market from the collectivist systems.

650 S Breyer, *Regulation and its Reform* (Harvard, 1892); R Baldwin et al, op cit.

651 A Ogus, *Regulation: Legal Form and Economic Theory* (Oxford, 1994).

price levels and quality, or insufficient information to consumers, or inadequate provision of public goods.[652] The main features of the various theories are as follows.

The public interest or functional analysis theory holds that the state acts in the public interest to remedy market imperfections, and that expert regulators can be trusted to act in the public interest and efficiently. However, information deficiencies may prevent regulators from acting rationally. This theory postulates that agencies were created to serve the interests of the industries they regulate, especially by helping them to achieve monopolies in the market.[653] It is true that one function of the Commission[654] is to sponsor industry, with the goal of enhancing the economic competitiveness of the Community. There is no evidence, however, that European product regulation was created by industry so as to achieve lower levels of product safety, as a result of having to comply with lesser regulatory requirements. On the contrary, the evidence of this study is that extensive regulatory requirements have been introduced with the specific aim of ensuring a high level of safety,[655] and the historical evidence indicates that virtually no sectors were instrumental in positively seeking the introduction of regulation.[656]

In contrast, interest group theory argues that regulation is the product of competitive struggles involving different interest groups and the state:[657] this may be viewed as either collaborative or less benign, depending on the balance achieved.[658] The theory of regulatory capture takes this further and argues that regulation is driven by the maximisation of rational self-interest of policy participants, and agencies can adopt bias toward the interests of those who they are intended to regulate,[659] whether as a result of progressive 'life-cycle' alignment.[660] The manifestations may be more powerful lobbying by the regulated than by the public, co-option by industry of expert advisers to regulatory agencies,[661] or revolving of personnel between industry and regulatory agencies.[662] Some argue that capture and contest theories are of limited use, and that regulation involves an

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652 G Majone, *Regulating Europe*, Routledge, 1996, p28-29.

653 G I Stigler, "The theory of economic regulation", *Bell Journal of Economics and Management Science*, 1971, 2:3-21.

654 Or, at any rate, part of the Commission, namely the Directorate-General for Enterprise, although the Commission (sometimes acting through other Directorates-General) is also required to ensure that a competitive market exists and that consumers are protected.

655 EC Treaty, Article 95.

656 The medical devices sector seems to be virtually the only sector that actively sough the introduction of comprehensive regulation in the late 1980's, having been previously largely unregulated, and this was with a view to benefiting from perceived commercial advantages the internal market with no consideration of safety issues: personal communication with MJCG Carlisle, Director of EUCOMED.

657 G I Stigler, supra.

658 One indicator is the extent to which there exist organised lobbying or interest groups: see ch 18.

659 Ogus, p 94.

660 M Bernstein, *Regulating Business by Independent Commission*, Princeton University Press, 1955.

661 B Owen and R Braeutigam, *The Regulation Game: Strategic Use of the Administrative Process*, Cambridge, Massachusetts: Ballinger Publishing Company 1978.

662 "pantouflage" relationship: J Braithwaite, *Corporate Crime in the Pharmaceutical Industry*, Routledge and Kegan Paul, 1986; L Hancher and M Moran, "Conclusion: organising regulatory space" in L Hancher and M Moran (eds), *Capitalism, Culture and Economic Regulation* (Clarendon, 1989) pp 271-300.

unavoidable intermingling of shifting public and private characteristics in a shared "regulatory space".[663] However, allegations of regulatory capture have been noted above in relation to medicines agencies.[664]

In considering the regulation of safety in the light of the above background, various points should be noted. First, it is misleading to assume that one group (commercial operators) will always seek to diminish safety or expenditure on it (larger commercial enterprises with reputations for safety can be expected to aim to protect their reputation and may press for increases in regulation that will entail increased costs for competitors), or that another group (consumers) will always try to maximise safety and expenditure on it (availability and price of goods must also be considered). The achievement of safety can be both a social policy aim and a value that is shared by the different actors, albeit perhaps for different reasons. Secondly, the existence of product agencies at both European and national levels complicates the mechanisms and may act either to increase competition and to increase or decrease safety. Thirdly, there is a high and increasing technical and scientific content to decisions on safety matters, and a potential dislocation between such values and individual, public, or political valuations of safety.[665] Fourthly, there exists an increasing corpus of scientific and technical staff within regulators and as expert advisers to agencies, who will tend to maintain competence and consistency.

In the context of safety, the public interest is clearly that of maintenance and improvement in public health and the avoidance of injury to individual citizens.[666] Safety, therefore, has to be considered at both the macro level of public health and protection and the individual level of each citizen. Few would doubt a general proposition that there exists the *potential* for conflict between safety and commercial pursuit of profit,[667] or that regulation is the appropriate mechanism to control this.

A market will always deliver *some* level of safety,[668] for example through mechanisms of the comparative cost of products that include different safety features, or the cost implications of a product liability mechanism, or the cost to consumers of accidents and the ability to avoid them, or the cost advantages of maintaining producers' reputations. Nevertheless, the purpose of regulatory intervention on safety grounds remains the maintenance and restoration of perceived balance, and

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663 L Hancher and M Moran, 'Organising Regulatory Space' in L Hancher and M Moran (eds), *Capitalism, Culture, and Regulation* (Oxford, 1989).

664 See ch 4.

665 This is discussed further in ch 19.

666 or at least the avoidance of avoidable injury.

667 the obvious, and indeed the seminal, event which spurred on European regulation was the horrific deformations of children born to mothers who took thalidomide as a therapeutic for morning sickness, marketing being virtually unregulated in Europe but prevented in USA by the existence and action of the regulatory agency: see H Teff and CR Munro, *Thalidomide: the legal aftermath*, (Saxon House, 1976).

668 W K Viscusi, *Regulating Consumer Product Safety* (American Enterprise Institute for Public Policy Research, 1984).

the achievement of a level of safety that is judged acceptable by the particular society that is not achieved without such intervention. The difficult consequential issue that arises is that of quantification: how much safety should or does each group of actors aim to achieve; and what happens when these values differ? These issues will need to be considered below.

The economic arguments on safety regulation

A classic economic analysis of consumer safety regulation is that of Asch in 1988,[669] whose analysis for the justification for government intervention in market behaviour was, it is suggested, based on two assumptions: firstly, the theory that commercial operators' behaviour would otherwise provide an unacceptable level of safety and, secondly, that such intervention would rectify such failure and provide an acceptable level. Asch pointed to a number of difficulties with both assumptions. In relation to the first issue, he asserted that unregulated markets will provide some level of safety, and that the key issues that arise are over the extent to which that level is considered to be unacceptable (the degree of "failure"), which requires a statement and comparative measurement of both the prevailing and the notionally acceptable levels. He concluded:

> "What economists ... look for as a justification for intervention is failure so basic and costly that when we substitute the judgment of a government agency for that of the market, outcomes are likely to improve.
>
> The prevention of all consumer accidents and injuries – "zero risk" – is neither a realistic nor a useful goal. To eliminate all risk is not only impossible in a practical sense, it is an objective whose pursuit is likely to become extravagantly expensive and highly inefficient. Choices must therefore be made. To those who may object that it is heartless to put a "price tag" on human safety, the response is clear: The inefficient pursuit of safety in one area must diminish our ability to pursue safety efficiently in other areas. The net result of the inefficiency will therefore be more injuries, more deaths, and more suffering in the unprotected areas."[670]

The cost of intervention therefore becomes an issue, as does the value justification for intervention – how much intervention is worth doing and what value will it produce (quantity issues)?[671] There is a further difficulty over the extent to which consumer behaviour will alter as a result of intervention (especially as a result of the provision of more information)[672] so as to select the "appropriate" non-market-failure result. Individual consumers' misperceptions may be influenced or over-ridden by personal taste or preference, and it cannot be concluded that misperception merits public

669 P Asch, *Consumer Safety Regulation* (Oxford, 1988).
670 Ibid, p 43.
671 Ibid, p 59.
672 See ch 10.

intervention: there is considerable empirical difficulty in quantifying the costs of misperception, and in concluding that either more or less safety regulation is called for.[673]

Given that public intervention has costs and benefits, the desirability of intervening in any given case requires estimation of these magnitudes,[674] but the issue of where the line should be drawn can be the subject of "vehement disagreement that has a good deal to do with ideology and much less to do with analysis of evidence."[675] Asch concludes:

> "Some weighing of benefits and costs is prerequisite to sensible answers..... The "production" of safety...can consume enormous resources and does not inevitably yield major gains."

Asch states that the result of his analysis is that the impact of safety regulation is substantially smaller than its advocates believe[676] and that the crucial issue is whether collective risk/safety decisions are being made in the most reasonable ways. In the absence of empirical data that would enable us to evaluate whether cost/benefit and safety decisions are being made on the most rational basis:

> "A persuasive rationale for government intervention must rest on the *belief* that the market, or human participants in the market, fail to react to risks effectively or "rationally." The issue is not the mere existence of risk but rather the inability to respond reasonably to the problems it poses."[677](emphasis added)

It may be concluded that *public* safety and the *public perception* of what are acceptable levels of safety and of expenditure on regulatory intervention are matters that society places responsibility on politicians, so the answers to the above questions of degree (what is the prevailing acceptable level of safety? how much expenditure?) are political issues.[678]

If it is true, or seriously to be suspected, that safety regulation has little impact then it indicates that there may be over-regulation, which imposes unnecessary costs and delivers insufficient benefits. The logical response would be to seek empirical evidence to establish whether this is the position. However, it is striking that, given the huge increase in Community safety regulation since Asch's publication in 1988, there has been virtually no attempt to quantify any of the relevant measurables, so as to undertake cost-benefit analyses or to set targets for increases in safety which could have

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673 Ibid, p 99.

674 Ibid, p 93.

675 Ibid, p 141.

676 Ibid, p 147. W K Viscusi, *Fatal Tradeoffs: Public & Private Responsibilities for Risk* (Oxford, 1992), ch 13 concluded that the available data failed to provide any clear-cut evidence that the actions of the US Consumer Product Safety Commission had a significant beneficial effect on product safety, and that individual actions are an important component of the accident-generation process.

677 Ibid, p121.

678 A significant manifestation of this is the adoption in the legislation of the undefined concepts of "safety" and of "a high level of protection", which are discussed in ch 19.

provided measures of success or failure:[679] this observation is surprising given that the founding concern of European regulation is with the efficiency and competitiveness of markets, which may be expected to require that levels of expenditure (whether by economic operators, regulators or consumers) are monitored so as to be reduced to optimal levels.

The political balance: Who has the costs and benefits of safety?

If safety issues are ultimately political, it is important to understand the forces at work. Peltzman argues that regulatory outcomes are determined by the political equilibrium - the balance of opposing interests, depending on organisational costs faced by competing groups.[680] Wilson argues that if the benefits of regulation are diffused but the costs are concentrated on private interests, then regulatory intervention is likely to stall; conversely, if the benefits are concentrated on a private interest group but the costs are diffused, then regulation serves the interest group; and if both costs and benefits are concentrated between competing interest groups, the regulator acts as an arbitrator.[681]

In whose interest is the achievement of safety? Clearly, people who may be directly injured (users and bystanders) are direct beneficiaries. But it can also be argued that both producers/distributors and governments are also beneficiaries; producers because consumers' perception of the level of safety of product affects the level of consumption, provided there is adequate transparency of information on the former, and governments because the level of safety influences demand for expenditure on healthcare and also income through VAT receipts on products sold. Thus, a consumer perception that a product is unsafe will depress sales and VAT and may increase healthcare expenditure. It has also been argued that regulatory refusal to approve a product (specifically, the US Food and Drug Agency's refusal to licence thalidomide) not only protects public health but also protects the manufacturer by preventing it going out of business through the crippling lawsuits which would have followed widespread use of the product.[682]

In order to consider Wilson's analysis, one should also determine who has the cost of meeting regulated safety requirements. The primary cost burden, or at any rate the obligation to finance the cost, falls on industry. In some sectors the cost can be enormous,[683] although it may vary

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679 Ibid, p 148.

680 S Peltzman "Toward a more general theory of regulation", *Journal of Economics and Law*, 1976, 19: 211-40.

681 J Q Wilson (ed), *The Politics of Regulation*, (New York: Basic Books, 1980).

682 J Braithwaite, *Corporate Crime in the Pharmaceutical Industry*, Routledge and Kegan Paul, 1986.

683 The amortised cost of research and development of a new chemical entity medicinal product is calculated as Euro 895million in 2002: Communication from the Commission: *A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action* COM(2003) 383, 1.7.2003, fn 11.

considerably between sectors.[684] But consumers also contribute to safety costs through paying for products, and having the option of choosing more or less expensive products with respectively higher or lower levels of safety features, and perhaps a greater or lesser extent of safety testing.

On Wilson's theory, it can therefore be argued that as the primary safety benefits of regulation fall on consumers and the primary costs fall on industry, but both sectors also have secondary benefits, his third situation of equilibrium prevails and regulators act as arbitrators. However, both benefits and costs could be viewed as to some extent diffused, which may either reinforce or diffuse the regulators' arbitration function. It would follow that the achievement of equilibrium would tend to be enhanced by factors which increase the concentration of costs on industry and of benefits on consumers, or vice versa.

The existence of industry and consumer interest groups who influence Community legislation is noted in chapter 18.[685] There is a numerical preponderance of industry groupings. Complaints are heard from consumer lobbyists of lack of resources and access to expertise in technical areas. Factors which would tend to strengthen the equilibrium would be if public pressure, perhaps brought about by consumer organisations but usually exerted though media criticism, highlighted a safety issue, which thereby threatened to increase industry's costs through taking action on the product or its brand and to increase benefits to consumers through increasing their safety. There are many examples of where this can occur in practice.[686]

The theory of social regulation

Ogus[687] has distinguished between economic and social forms of regulation. We have seen in chapter 3 that the constitutional justification and purpose of Community product regulation is in fact economic, and that social regulation, dealing with such matters as health and safety, environmental protection, and consumer protection, is formally incidental. This may be expected to give rise to a conflict of goals and failure to achieve the social purpose. Should intervention that has a social purpose not state that purpose and be judged on its ability to deliver it? Is it not the case that product regulation is primarily about safety rather than market aspects? Further, Viscusi argues

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684 Toys would be at the lower end.

685 A division of political influence can also be detected within the European Commission. Broadly, consumer issues are championed by the Directorate-General on Health and Consumer Affairs (SANCO) and industry issues are championed by the Directorate-General for Enterprise. Others, such as the Directorate-General on the Internal Market regard themselves as neutral (conversations between the author and officials) and collegiate consensus is reached within the College of Commissioners.

686 Compare the approaches of D Wilson and L Andrews, *Campaigning: The A-Z of Public Advocacy* Hawksmere, 1993) and M Seymour and S Moore, *Effective Crisis Management: Worldwide Principles and Practice* (Cassell, 2000).

687 A I Ogus, supra.

that government should not intervene in regulating product safety in the absence of established evidence that there has been market failure to provide the desired level of safety.[688]

Ogus states that social regulation tends to centre on two types of market failure.[689]

> "First, individuals in an existing, or potential, contractual relationship with firms supplying goods or services often have inadequate information concerning the quality offered by suppliers; in consequence, the unregulated market may fail to meet their preferences. Secondly, even if this information problem does not exist, market transactions may have spillover effects (or externalities) which adversely affect individuals who are involved in the transactions.
>
> To deal with these problems, policy-makers can choose from a range of regulatory instruments, classifiable according to the degree of state intervention required. At the end of the spectrum associated with low intervention, we can identify three regulatory forms: information regulation..., forcing suppliers to disclose details concerning the quality of their goods or services; "private" regulation..., imposing obligations which nevertheless can be enforced only by the individuals for whose benefit they have been created; and economic instruments..., which ... are not coercive but rather induce desirable behaviour by financial incentives. At the other end of the spectrum, we find the highly interventionist instrument of prior approval...; this prohibits the undertaking of an activity without a licence or authorization issued by an agency. Between the extremes lies the most frequently employed form of regulation – sometimes referred to as "command-and-control" – in which standards, backed by criminal sanctions, are imposed on suppliers..."

This general description of a pyramid of regulatory strategies[690] can largely be applied to the forms of safety regulation if we substitute "safety" for "quality" above. All product safety regulation requires information disclosure. Medicinal products are subject to the high intervention technique, not only pre-marketing but also post-marketing, plus the medium techniques. The New Approach is generally of the medium type. The "private" and economic instruments techniques, such as franchising or "regulation by contract",[691] are not used in safety regulation. Self-regulation, through delegation of responsibilities to producers, has considerable influence in safety regulation. Guidelines promulgated by regulators and standards issued by the official standardisation bodies are also important features, but there is little evidence of industry codes of conduct in the safety area.[692]

The important topic of information regulation is discussed in chapter 10. In its pure form, Ogus states that the "compliance with standards" technique allows the activity (marketing a product) to

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688 W K Viscusi, *Regulating Consumer Product Safety* (American Enterprise Institute for Public Policy Research, 1984).

689 A I Ogus, supra.

690 I Ayres and J Braithwaite, *Responsive Regulation – Transcending the Deregulation Debate* (Oxford, 1992), 35.

691 T Daintith, 'Regulation by Contract: The New Prerogative' (1979) *Current Legal Problems* 41; H Collins, *Regulating Contracts* (Oxford, 1999); although as discussed in ch 5 private contracts are important New Approach mechanisms between manufacturers and notified bodies.

692 Trade association codes of conduct exist on promotional aspects, such as the Prescription Medicines Code of Practice Authority's Code, and some codes exist on recall issues, such as the Society of Motor Manufacturers and Traders' Code of Practice on Vehicle Safety Defects, but the latter are fairly restricted and likely to be superceded by the 2001 GPSD amendments.

take place without any *ex ante* control, but the supplier who fails to meet the defined standards of quality commits an offence.[693] He divides standards into three types:

> "A *target standard* prescribes no specific standard for the supplier's processes or output, but imposes criminal liability for certain harmful consequences arising from the output. A *performance* (or output) standard requires certain conditions of quality to be met at the point of supply, but leaves the supplier free to choose how to meet those conditions. A *specification* (or input) standard can exist in either a positive or negative form: it compels the supplier to employ certain production methods or materials, or prohibits the use of certain production methods or materials."[694]

All product safety regulation that requires that products be safe or comply with stated essential requirements adopts a target standard.[695] The difficulty here is that in prescribing a general principle such as "safety" one achieves flexibility but empowers regulators with considerable discretion that impedes public scrutiny and leaves economic operators uncertain as to what is required of them.[696] One needs to be careful over terminology, since compliance with a "European harmonised standard" is voluntary and failure in compliance by itself imposes no criminal consequence, but may be good evidence of failure to comply with the legal safety standard. The standard-setting process can be subject to pressure from private interests (whether economic operators or public/political) seeking to influence or capture it.[697] Again, an empirical approach is not in evidence: Ogus concludes that costs are generally easier to quantify than benefits, and cost-benefit analysis of the value of standards involves some degree of subjective, perhaps ideological, judgment.[698]

Selecting the right regulatory approach and techniques

Consistent with the above analysis, Part Two found that the principal techniques that regulators can employ in relation to safety are: requirements for provision of information, prior approval of marketing, imposition of record-keeping, undertaking inspections, imposing penalties for non-compliance, requiring the temporary or permanent cessation of marketing, and requiring the recall of products distributed.[699]

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693 Ogus, supra, p 150.

694 Ibid, p 151. Viscusi described most US standards in force in the early 1980s as specification or performance types: W K Viscusi, supra, ch 2.

695 This constitutes a move away from historical reliance on performance and specification standards. A possible rationale for this change in policy relates to producers' need for deregulation and ability to innovate as opposed to the market protectionism that was a consideration before the creation of the internal market: see Ogus, p198.

696 Ibid, p 170.

697 Ibid, p 171 et seq.

698 Ibid, p 160; S Kelman, "Cost-Benefit Analysis: An Ethical Critique" (1981) 33 Stan. LR 387. M W Jones-Lee, *The Economics of Safety and Physical Risk* (Basil Blackwell, 1989) set out an evaluative approach and calculations.

699 The economic impact of these techniques will vary, although indirect costs should not be overlooked, such as publicity that adversely affects reputation or the cost of measures necessary to ensure future compliance. It is nor difficult to see that recall will often have the greatest cost.

Part Two also found that not all techniques are found in every product regime. Why should this be? The choice of which technique to adopt for a particular product type is influenced by several variables.[700] The cultural and behavioural variables that are identified in theoretical writings include:[701] the perception of the magnitude of social losses that can result from failure (perceived to be large for medicines); the influence of publicity and the media on public feeling and political action in response to major incidents; perceived inadequacy of consumer responses to increased information; paternalism; and pressure from industry or consumer groups. Each of these factors can be identified in relation to product safety regulation.

Diver[702] proposed a normative model for rule precision, which seeks to explain why optimal precision varies from rule to rule.[703] First, he distinguishes three quality dimensions of rules: transparency,[704] accessibility,[705] and congruence.[706] Secondly, the variant of regulatory precision is selected that maximises social utility dependent on the costs and benefits that arise under four categories: rate of compliance, over- and under-inclusiveness, costs of rulemaking, and cost of applying the rule. Such an analysis illuminates the use of different approaches for different product sectors. One finds a pyramidal structure of safety rules, headed by the policy objective (safety), underpinned by a layer of essential requirements (or essential tests), and then standards or explanatory guidelines, in which the degree of precision increases at lower levels, moving from generalised purposive principles towards greater specificity.[707]

Black points out that general rules (such as "products must be safe") can have specificity where there is shared understanding as to meaning:[708] whilst politicians and the public may consider that the standard is absolute safety, regulators, firms and lawyers will qualify this concept, so a disconnect may develop. This illumination points to the ideal of having a shared understanding in relation to the meaning of safety.

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700 Se R Baldwin and M Cave, *Understanding Regulation* (Oxford, 1999), ch 4.

701 Ogus, p 191; R Hirshhorn, "Regulating Quality in Product Markets", in D Dewees (ed), *The Regulation of Quality* (1983); W K Viscusi, *Regulating Consumer Product Safety* (American Enterprise Institute for Public Policy Research, 1984); P Asch, *Consumer Safety Regulation* (Oxford, 1988).

702 C S Diver, 'The Optimal Precision of Administrative Rules' (1983) 93 *Yale Law Journal* 65-109.

703 The models of enforced self regulation, under which each company is compelled to write its own set of rules that a regulator can then enforce, or partial-industry intervention are not found in Community product safety systems: see I Ayres and J Braithwaite, *Responsive Regulaion* (Oxfrod, 1992). There are, however, strong elements of self-customisation, such as in the New Approach system. See P Selznick, 'Self-Regulation and the Theory of Institutions, in G Teubner, L Farmer and D Murphy (eds), *Environmental Law and Ecological Responsibility: The Concept and Practice of Ecological Self-Organisation* (John Wiley & Sons Ltd, 1994).

704 The degree of clarity and intelligibility of the wording chosen.

705 The degree of applicability of the rule to concrete situations without excessive difficulty or effort.

706 The extent to which the rule produces the desired policy objective.

707 Further, one observes use of generalised language in Community instruments but some greater precision in national transpositions that provide for criminal sanctions. J Black, *Rules and Regulators* (Oxford, 1997); and J Black, 'Using Rules Effectively' in C McCrudden (ed), *Regulation and Deregulation* (Oxford, 1999) and others point out that different formulations of rules will have enforcement consequences, with general rules facilitating an educative approach to enforcement, and specific rules a prosecution-based approach.

708 J Black, op cit.

Hood, Rothstein and Baldwin have recently argued that regimes that regulate risk may be composed of varying combinations of pressures, and that existing theories offer complementary rather than rival accounts, with no single theory explaining all or any regimes.[709] They conclude that a viable control system must possess information-gathering, standard-setting and behaviour-modification components with clear linkages between them. However, achieving coherent integration between design and operation of regulatory systems is frequently lacking.[710] They argue that since regulatory processes involve contradictory values, those values should be built into the administrative architecture so that they are constantly able to be juxtaposed in an open process of institutionalised debate, and also that transparency in the process of design of a regulatory assessment regime is important, since this involves weighing principles that are mutually incompatible.

The concept here is one of incommensurability. In the context of product regulation, incommensurability is a means of reconciling the fact that there are items within the hazard-benefit equation that are valued differently by different people, and that a legal system which intrinsically incorporates such incommensurabilities must have transparency, accountability to stakeholders, and the opportunity for vigorous public debate. These qualities will permit the system to continue to operate in the absence of consensus.

Conclusions

The above theoretical considerations illuminate the reality of Community product regulation as found in Part Two. Theoretical analysis provides a significant explanation of why different regulatory mechanisms are adopted for different product sectors: the answer is significantly influenced by public perceptions of risk, and this matter will be examined further in chapter 19.

However, academic analysis of both economic and social regulation emphasises the importance of quantification in answering the fundamental questions: given that markets will produce some level of safety, can sectors be identified where the level is unacceptable? What level of safety is acceptable? What cost of regulation should we allocate to achieve what incremental increase in the level of safety? What incremental increase or decrease in safety does the system actually produce, and at what cost – is the mechanism working, efficient and justified? The following chapters will need to examine the extent to which quantification exists, or whether the American experience reported by Asch and Viscusi, of reliance more on idealism than empiricism, is mirrored in Europe.

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709 C Hood, H Rothstein and R Baldwin, *The Government of Risk* (Oxford, 2001). The multi-causal theories they examine are 'market-failure' pressures, 'opinion-responsive' pressures, and 'interest-driven' pressures, plus 'tombstone-ability' (the capacity of a risk to produce deaths or suffering through dramatic catastrophies).

710 This danger is clearly signalled in relation to the supranational, multi-actor regimes of European safety regulation, notably in relation to market surveillance and enforcement issues, as found in chs 18 and 12.

The point made by Hood, Rothstein and Baldwin is highly relevant. To what extent are contradictory elements and values incorporated into the regulatory architecture and into what is meant by safety, and how costs and benefits are valued? The above analysis has found that there are potent contradictory values within Community safety regulation. The major legal contradiction is between the formal market goal of the regulatory legislation and its actual social goal of achieving safety. There is enormous scope for differences of views on what constitutes an acceptable level of safety in particular circumstances, and what constitutes "a high level of protection". There is also the possible "political" conflict between the goals of interest groups, such as consumers, producers and regulators. Accordingly, the system can only continue to operate if there is transparency, accountability to stakeholders, and the opportunity for vigorous open debate.

In order to examine such issues further, the next step is to analyse the context in which such issues are debated at Community level, the identity of the principal actors, and the institutional context in which they operate.

18. THE MECHANISMS OF GOVERNANCE OF THE INSTITUTIONS INVOLVED

The purpose of this chapter is to critically analyse the actors who are involved in Community regulation. Who are they, how do they operate and inter-relate, what is the nature of the controls to which each is subject, and are there weaknesses in their constitutional legitimacy or ability to deliver product safety? The analysis begins by summarising the actors who have been identified in Parts One and Two. It then confirms the theoretical tests for constitutional legitimacy of rules, before applying these tests to each actor, and drawing conclusions.

The Community's multi-actor systems

The emergence of the regulatory state within the Community has been swift, occurring since the 1970s.[711] This expansion of regulation has occurred at a time when the principal politico-economic policies have been *de*-regulation, liberalisation and privatisation, with a reduction in state expenditures. Secondly, the mechanisms that have been adopted have involved a proliferation of regulatory bodies at Community and national levels. The various actors involved in product safety decisions are summarised at Table 9.

How do the complex[712] mechanisms for governance that have evolved in the Community operate and can they be expected to achieve the safety goal? The mechanisms have been analysed by political scientists as an unique, innovatory,[713] developed system of supranational governance,[714] in which important features are:[715] a multi-level system of governance, being a confederation located between inter-state and intrastate patterns of rule;[716] systemic properties that balance the conflicting dynamics of "cooperative confederalism" and the territorial principle, and are particularly subject to evolution over time; reliance on both formal rules and informal procedures and "rules of the game";[717] regulation as the predominant form of EC policy; law as the predominant pattern of rule; a fragmented policy-making machinery, with weak horizontal coordination in the Commission, and

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711 G Majone, *Regulating Europe* (Routledge, 1996); G Majone, "The Rise of the Regulatory State in Europe", *West European Politics* (1994) 17:3, 77-101.

712 Contrast the United States where the federal regulatory system is formalised and legalistic, administered by powerful agencies having rule-making, enforcement and sanctioning powers, surrounded by a strong lobbying phenomenon: see S Breyer, 'Regulation and Deregulation in the United States: Airlines, Telecommunications and Anti-Trust', in G Majone (ed), *Deregulation or Reregulation?* (Pinter, 1990).

713 A Stone Sweet, W Sandholtz and N Fligstein, *The Institutionalization of Europe* (Oxford, 2001).

714 Amongst a large literature see W Sandholtz and S Stone Sweet, *European Integration and Supranational Governance* (Oxford, 1998).

715 K Armstrong and S Butler, *The governance of the Single European Market* (Manchester, 1998), chapter 3.

716 M Forsyth, *Union of States: The Theory and Practice of Confederation* (Leicester UP, 1981).

717 See further D G Baird, R H Gertner and R C Picker, *Game Theory and the Law* (Harvard UP, 1994).

discrete specialised advisory committees;[718] policy-makers following the rules prevailing in "their" governance regime; governance regimes that each reflect a particular policy inheritance.

It is apparent from the analysis undertaken above that these comments on market regulation equally hold true for safety regulation. As Armstrong and Butler have analysed, some parts of the programme have vested regulatory authority in the supranational institutions themselves; others rely on national authorities to enact and implement legislation; still others, notably on technical standards, push the burden of responsibility into supervised self-regulation.[719] This multiple approach requires an examination of the various institutions to see how they act in the safety area, and whether there are flaws in the design of this cooperative confederation of actors.[720] Remarkably, commentators generally agree on a positive evaluation of the quality of European governance.[721]

Tests for legitimacy of rules

How are we to judge the constitutional legitimacy of rules on product safety? Five rationales have been propounded by Baldwin for the legitimacy of rules:[722]

1. *Legislative mandate*: is there assent of the people through democratic accountability?
2. *Accountability or control*: is the exercise accountable through oversight, with rights of participation, consultation or openness?
3. *Due process*: are there procedures that imply respect for the interests of the people affected?
4. *Expertise*: is a balanced judgment able to be formed on polycentric issues, especially where expertise is required?
5. *Efficiency*: are the stated objectives being achieved in an efficient manner, and are individual actions economically efficient?

Since the basis of product regulation in all sectors is legislation, the legislative mandate claim is as strong as for any other item of Community legislation. The major caveat here is that much of the

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718 In the safety context, policy on rule-making emerges from the Commission, but involving influence both before and during the process by the Member States, the Parliament and interested groups; policy on enforcement currently lies primarily with Member States and their authorities, but can be influenced by the other actors. The Commission is fragmented by responsibility for different product sectors resting with different Directorates General: medicinal products, new approach, cosmetics, biocides resting with different units of DG Enterprise, GPS and tobacco with DG Sanco.

719 K Armstrong and S Butler, *The governance of the Single European Market* (Manchester, 1998), p 6.

720 As Majone suspected: G Majone, "The Rise of the Regulatory State in Europe", *West European Politics* (1994) 17:3, 77-101.

721 C Joerges, "The Law's Problems with Governance of the European market" in C Joerges and R Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford, 2002).

722 R Baldwin, *Rules and Government* (Oxford, 1996); R Baldwin and M Cave, *Understanding Regulation* (Oxford, 1999), ch 6.

language of essential requirements expresses generalised objectives rather than detailed rules, which can be unclear[723] and therefore subject to interpretation, whether by competent authorities or the courts. There is ample scope for Member States' authorities and courts to differ in interpretation on such issues.[724] The authorities' record of issuing guidelines so as to achieve consistent interpretation throughout the Community is reasonable and improving, but this is an issue that requires review.

Various aspects are analysed in more detail below, but some general points can be made straight away. The multi-level official Community mechanisms mean that issues of accountability and due process in the operation of the rules will arise: this indicates that provision of safeguards through uniform mechanisms of oversight and accountability may be needed. Further, all of the measures lean heavily on the expertise claim, whether through the use of committees of experts in the medicines, cosmetics and biocides systems or through delegation of responsibility to notified bodies and manufacturers themselves in the New Approach. Finally, the two aspects of the efficiency claim present considerable difficulties, principally because they require empirical evidence to test whether they are satisfied, and this is largely lacking.

Majone argues that a mode of regulation that emphasises independence and expertise will produce more incisive regulatory policies, and that major advantages of a self-regulatory organisation (SRO)[725] will include the ability to command a greater degree of expertise and knowledge of practises, and less formalisation of rules (associated with lower cost, quicker adaptation, and more flexible enforcement),[726] but the disadvantages include a serious risk of regulatory capture and uninformed monitoring, although a two-tier system where a public agency acts as regulator of regulators and SROs handle day-to-day rule making may overcome the latter.[727] Noting strong evidence from the United States in favour of active political control, he concludes that delegation of policy-making powers to expert agencies need not entail a loss of democratic accountability, and that agencies with the most stable outputs have been those that are independent regulatory commissions. Further, regulators can be monitored and kept politically accountable by means of a combination of

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723 For example the requirements to include "any special warnings" in product information, discussed in ch 10.

724 C Hodges, 'The European Legal System: Harmonisation or Chaos in Product Regulation?' [2002] BLI 219. National courts may be reluctant to interfere with expert judgments on judicial review – see chapter 3. The medicinal products systems have progressively introduced mechanisms for reaching unanimity of the authorities on regulatory decisions.

725 This may apply to some extent to the Commission, Community Agencies, competent authorities of Member States, notified bodies, and manufacturers.

726 G Majone, *Regulating Europe* (Routledge, 1996), p 23.

727 Ibid, pp 23-27. This may be applied to the role of the Community Food Agency or EMEA in supervising national competent authorities, or to the relationship of competent authorities, notified bodies and manufacturers under the New Approach.

control instruments: oversight by specialised congressional committees, presidential power of appointment, strict procedural requirements, professional standards, public participation and judicial review.[728] It will be seen from the analysis of the Community actors which follows that these features of political control are absent from the Community scheme. The question, therefore, arises whether such political oversight is needed: it is suggested that these mechanisms have disadvantages of cost and increased politicisation of safety, and need should be tested against empirical evidence of failure in performance. Public accountability may, however, be exercised through non-institutionalised mechanisms, and vigorous public debate on safety issues is carried out in the media. In order to be effective, such debate requires access to accurate information (transparency) and to be informed by expert comment and opinion: these points are taken further in chapter 29.

Majone contrasts the distinction between efficiency and redistribution. He concludes that if *efficiency* is to be adopted as the standard by which regulators are to be evaluated, then regulatory instruments should not be used for redistributive purposes. Conversely, decisions involving significant redistribution of resources cannot be legitimately taken by independent experts, but only by elected officials or administrators directly responsible to them. "Only a commitment to efficiency, that is, to the maximization of aggregate welfare, and to accountability by results, can substantively legitimise the political independence of regulators."[729] It is difficult to see how safety regulation is about redistribution policy rather than efficiency, although its effects may involve expense. Maximization of aggregate welfare is clearly the primary goal, and it follows that accountability by results is important. Such accountability may mean the avoidance of public disasters, although this may be fortuitous, but one comes back to the issue of quantification of whether a regulator has delivered a rise in the prevailing level of safety, and this is an issue that may not be dependent on market failure but merely the achievement of a rise in the previously prevailing level of safety.

The Commission

The Commission can be viewed as the agent of the Member States, exemplifying the principal-agent theory of delegation in circumstances that offer principals advantages of reduction in the transaction costs of policy-making by providing policy-relevant information, and allowing principals (the Member States) to commit credibly to their agreements by offering an increased chance of

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728 Majone, p 39. "When such a system works properly, no one controls an independent agency, yet the agency is "under control". T Moe "Interests, institutions and positive theory: the politics of the NLRB", *Studies in American Political Development* 2: 236-99."

729 Ibid, p 295.

compliance.[730] In addition to formal initiation of legislation, the Commission plays important roles[731] in administering policy, acting as guardian of the treaties,[732] acting as supranational conscience, and mediation between Member States.[733] The Commission has retained[734] a central role in coordination of oversight of the operation of product legislation, through chairmanship of expert working groups and formal committees in all sectors, and in the medicines sector through the power to grant and revoke marketing authorisations under the centralised system.[735]

The Commission differs from traditional, national regulators in that it has no direct responsibility for enforcement. Unlike the Federal agencies in the United States, there are no devolved offices in the Member States of the Commission or of centralised agencies that are responsible for product regulation or safety: the absence of supranational field agencies in the Member States means that national authorities retain responsibility for putting the Community provisions into practice.[736] The cost of regulatory compliance is primarily borne by manufacturers, and the costs of enforcement are borne by Member States.

Theoretical analysis is that supranational actors such as the Commission and centralised agencies are less at risk of capture by special interests in view of the sheer number of operators in a market of such size, and the effects of the need to maintain reputation and of the number of transactions will tend to produce high standards.[737] Indeed, the Commission is able to act as a policy entrepreneur.[738]

There is some political accountability to the European Parliament, but not much on operational aspects, and there would be little if the perhaps fortuitous regular review of legislation every few years were to be discontinued. This prompts the issue of whether there is a need for an oversight

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730 See M A Pollack, *The Engines of European Integration* (Oxford, 2003); M A Pollack, 'Delegation, agency, and agenda setting in the European Community' (1997) *International Organisation* 51 (1), 99-134 for a review of the advantages and costs of this principal-agent relationship.

731 K Armstrong and S Butler, op cit, ch 3.

732 Notably in this context monitoring compliance and initiating infringement actions against Member States for breach of the Treaty and failure to implement Community legislation.

733 Notably in relation to comitology.

734 The political/historical developments that led to Member States being willing to delegate authority to the Commission or a central agency has been said to lie in the low credibility of inter-governmental agreements and the mutual recognition approach, as discussed below: G Majone, (1994), supra, at 90; E Vos, *Instutional Frameworks of Community Health and Safety Regulation. Committees, Agencies and Private Bodies* (1999), at 60.

735 The latter being a classic "command and control" function. It is notable that this power is not exercised by the EMEA.

736 K Armstrong and S Butler, op cit, p 10.

737 G Majone, *Regulating Europe* (Routledge, 1996), pp 71, 72.

738 Ibid, p 75, and G Majone (1994) at 91, supra, citing the innovation of the technical Annex of essential requirements to Directive 89/392/EEC, which was drafted by a British inspector whose innovative ideas on risk assessment were adopted by the Commission. One would also point to the extensive expansion of Directive 2001/95/EC in post-marketing controls on both manufacturers and Member States.

committee of the Parliament. Accountability as between the Commission and Member States can take place regularly on an informal basis through ad hoc meetings or working groups, providing mechanisms for communication and convergence, but this is far from a transparent mechanism. A Parliamentary oversight mechanism may be resisted by Member States, but the justification is strong if safety is to be taken seriously, and the argument is strengthened where agencies are involved, as discussed below.

Comitology[739]

Comitology is a feature of the European system.[740] Two types of committees can be identified: those composed of independent experts giving high quality scientific advice on operational or policy issues to legislators or regulators, and those composed of civil servants of the Member States whose function may involve policy or implementational matters. Comitology has evolved partially because the Commission has limited infrastructure and resource, with little access to scientific and technical expertise, and partly because the Member States may maintain representation in decisions and a measure of oversight control over the Commission.[741]

Oversight committees can have advisory, management or regulatory functions.[742] Each committee involving Member State representatives reflects a different balance of power between the Commission and national officials.[743] They have evolved naturally over time,[744] and can be criticised[745] on the basis of lack of transparency[746] and public accountability, and of cost and

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739 An overview of comitology is given in C Docksey and K Williams, "The Commission and the Execution of Community Policy", in G Edwards and D Spence (eds), *The European Commission* (Harlow, Longman,), 117-45.

740 It is not necessary here to review the extensive number of committees and their functions and operation.

741 J Falke, "Comitology: From Small Councils to Complex Networks" in M Andenas and A Türk (eds), *Delegated Legislation and the Role of Committees in the EC* (Kluwer, 2000). M A Pollack, supra.

742 Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ L 184/23-26, 1999 repealing 87/373/EEC, OJ L 197/33. See G Haibach, "The History of Comitology" in M Andenas and A Türk (eds), *Delegated Legislation and the Role of Committees in the EC* (Kluwer, 2000).

743 K Armstrong and S Butler, op cit, p 74. Indeed, their function can be seen as an important element in this balance: R Dehousse, supra.

744 For the early history and evolution to the Comitology Decision, see K St C Bradley, 'Comitology and the Law: Through a Glass Darkly', (1992) *CMLR* 29: 693-721.

745 For an overview of a growing political theoretical literature see C Joerges, "The Law's Problems with Governance of the European market" in C Joerges and R Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford, 2002).

746 G de Burca notes that it is difficult to discern the part played by committees in the formulation and eventual adoption of measures: G de Burca, "The Institutional Development of the EU: A Constitutional Analysis", in P Craig and G de Burca (eds), *The Evolution of EU Law* (Oxford, 1999) 55, at 77. The committee system was criticised as opaque by F Stack and S Crampton, 'European governance: CA's response', *Consumer Policy Review* (2002) 12: 3, 106-113.

fragmentation,[747] as well as of questionable constitutional authority,[748] although some argue that the system performs well in both process and outcome terms.[749]

The scientific committees have been described as playing a crucial role in European social regulation through the integration of scientific and policy expertise, and as having significant potential for improving the quality of regulatory decision-making and overcoming the particularism of legal systems through scientific universalism.[750] In general, however, such committees are merely advisory, decision-making powers resting with the controlling agency or Commission, although the mechanism of consultation requires scientific issues and expert advice to be considered before a political decision is taken.[751]

Given that decisions on product safety and marketing can be complex and sensitive, the need to maintain confidence through transparency and due process requires review through public scrutiny and involvement, as well as for appropriate structures for hearings and appeals. Collective decision-making structures that are intended to be problem-solving will necessarily involve compromise[752] and this is inevitably a matter of concern in relation to safety issues, especially where the members of the committee may be subject to partisan views. There has been little evidence of conflict:[753] but some problems in the arena of safety should be expected.[754]

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747 G F Schaefer, "Linking Member State and European Administrations – The Role of Committees and Comitology" in M Andenas and A Türk (eds), *Delegated Legislation and the Role of Committees in the EC* (Kluwer, 2000).

748 S Schlacke, "Centralization and Europeanization of Administrative Implementation: Product Safety Legislation" in M Andenas and A Türk (eds), *Delegated Legislation and the Role of Committees in the EC* Kluwer, 2000).

749 J H H Weiler, "Epilogue: "Comitology" as Revolution-Infranationalism, Constitutionalism and Democracy" in C Joerges and E Vos (eds), *EU Committees: Social Regulation, Law and Politics* (1999).

750 G F Schaefer, "Linking Member State and European Administrations – The Role of Committees and Comitology" and A E Toller and C H Hofman, "Democracy and the Reform of Comitology" in M Andenas and A Türk (eds), *Delegated Legislation and the Role of Committees in the EC* (Kluwer, 2000). C Joerges "Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures" in C Joerges, K-H Ladeur and E Vos (eds), *Integrating Scientific Expertise into Regulatory Decision-Making, National Traditions and European Innovations* (Baden-Baden, 1997).

751 R Dehousse, "Misfits: EU Law and the Transformation of European Governance" in C Joerges and R Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford, 2002).

752 J Falke, "Comitology: From Small Councils to Complex Networks" in M Andenas and A Türk (eds), *Delegated Legislation and the Role of Committees in the EC* (Kluwer, 2000).

753 R Dehousse, supra.

754 An example is the different views taken by UK and Community authorities on the correct regulatory approach to new post-marketing information on the safety of a medicine, such as whether or not to ban it or what conditions to impose: see Case C-120/97 *Upjohn Ltd v The Licensing Authority established by the Medicines Act 1968 and others* ECR [1999] I-00223.

Almost every product sector has at least one committee although, as Table 11 shows,[755] committees (even in the same product sector) can report to different Directorates-General in the Commission: there would seem to be scope for confusion and inconsistency here and reporting lines could be rationalised.

Centralised Agencies

The theoretical justification for any agency is principally based on the claim to expertise, in dealing with highly complex or technical matters, and continuity, plus the consideration that, to the extent it has a rule-making function, this is inappropriate for governments or courts in the circumstances.[756] The existence of permanent structure and staff should lead to linear consistency of policy and decisions over time, where the agency either takes the decisions or is influential if they are formally taken by others.

Various further advantages can be postulated for agencies. First, if the agency covers different sectors that are subject to different regulation, systematic comparative consistency can be enhanced between the different approaches, so as to ensure equal levels of stringency of regulation, equal approaches to standards, costs, enforcement, and the provision of information, as well as reduce the risk of capture. Secondly, if the remit is sufficiently wide, there can be an ability to prioritise on safety issues and the expenditure of resources. Thirdly, there can also be an ability to undertake more pro-active approach to safety: Viscusi identified a tendency by the US authority to address short-term (acute) issues but not to engage with measuring and addressing chronic hazards.[757]

The arguments in favour of centralised agencies in the Community[758] include: the availability of the best quality of scientific and administrative talent; the aggregation of statistical information, which should lead to the earlier and increased reliability of identification of safety issues; the political

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755 This is a selection of committees that cover product safety issues: for a longer list see *List of Committees which assist the Commission in the exercise of its implementing powers* OJ C 225/2, 8.8.2000, which also states whether each committee operates according to the management, regulatory or advisory procedures of what is now Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ L 184/23, 17.7.1999.

756 G Majone, The Rise of the Regulatory State in Europe", *West European Politics* (1994) 17:3, 77-101, 84.

757 W K Viscusi, *Regulating Consumer Product Safety*, op cit.

758 Overviews of the 12 Agencies are E Chiti, "The Emergence of a Community Administration: The Case of European Agencies", *CMLRev.* (2000) 309; E Vos, "Reforming the European Commission: What Role to Play for European Agencies", 37 *CMLRev.* (2000) 1113. See also R Dehousse, supra. Chiti (op.cit.) identifies that the EMEA differs from other Community agencies in being responsible for social rather than economic regulation, directing private action towards a public interest. The European Food Safety Authority is not involved in pre-marketing decisions but its rationale is to exert pressure on, and provide a forum for benchmarking between, national agencies, particularly in their marketing surveillance activities.

achievement of consistency of decisions through similar populations in the Community; and potential reduction in transactional costs.[759]

The power of the Commission or a centralised agency in relation to the large size of the Community market, the need to maintain reputation, and the international nature of the membership should make regulatory capture of a Community agency less likely. A threat to effectiveness and reputation is the dependence for enforcement on national arrangements, policies and resources.[760]

If an agency were to make decisions, theoretical problems would arise over its democratic accountability and public involvement/control, since the officials are unelected and may not be responsible to elected individuals, although it is also argued that the insulation from the political process is an advantage, particularly when coupled with the advantages of continuity of expertise.[761] Since decisions on issues of safety have political and public aspects, it is, therefore, necessary for agencies that make such decisions to have a suitable measure of public accountability: this points towards oversight mechanisms by the European Parliament. Judicial review would be a partial solution to the democratic deficit, but the courts have decided that decisions that require complex assessments, such as on withdrawal of a marketing authorisation for a medicinal product, should be subject to the wide discretion of the competent authorities and the court may not substitute its assessment of the facts for that made by an authority.[762]

Community agencies do not, however, generally have formal decision-making powers, which are reserved to the Commission.[763] The function of safety agencies is the management of the Commission's functions,[764] although there is a strong cooperative role between agencies and national counterparts, usually through regular involvement in formal or informal committees. There is currently only one centralised agency in the sectors considered here, namely that for medicinal

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759 M G Faure, "Product Liability and Product Safety in Europe: Harmonization or Differentiation?" *KYKLOS* 2000 Vol 53, 4 467-508: Faure notes that economic theory suggests a variety of reasons why the local level is not best suited to take decisions and that central decision-making can lead to more efficient results.

760 This is a clear conclusion of ch 12.

761 G Majone (1994) and (1996).

762 Case C-120/97 *Upjohn Ltd* [1999] ECR I-223 and R *v Medicines Control Agency ex p Pharma Nord (UK) Ltd* [1998] 3 CMLR 109, CA, although judicial review is not so limited on other issues, such as labelling, that do not involve complex assessments: Case T-179/00 Court of First Instance, 3 July 2002.

763 Politically speaking, the Commission has guarded its power closely: R Dehousse, surpa, at 218. The argument has been that there is no power for delegation of executive powers under article 7 (ex 4) EC, which provides that the tasks entrusted to the Community shall be carried out by the named institutions of Parliament, Council, Commission and two Courts, each of which shall act within the limits of the powers conferred on it.

764 Thus, the EMEA and its committee, the CPMP, essentially prepare decisions for the Commission: see chapter 4.

products,[765] but an agency has recently been established in the food sector.[766] Chiti[767] concludes that the medicinal product system involves a double opposition: first, between scientific assessment and political-administrative decision and, secondly, between national and supranational interests. The system does, as he states, give scientific expertise primary influence on regulatory decisions, which raises issues of balancing other interests such as consumer/public/political. A further feature is the complex web of mechanisms involved.[768]

Should centralised agencies assume devolved decision-making powers?[769] In the area of safety, the arguments for this include increased transparency, the reduction of the risk of undue political interference in technical decisions,[770] and, importantly in the safety context, speed.[771] Theoretical principles would support agencies having enforcement powers:[772] even though current political sensibilities do not support this breach of subsidiarity, it can be supported on safety grounds.

Member State authorities

The historical approach to safety regulation has, of course, been mutual recognition between Member States. Mutual recognition has been an important principle[773] but has demonstrated limitations in practice.[774] The failure of mutual recognition is clearly seen in the demise during the

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765 The European Agency for the Evaluation of Medicinal Products (EMEA) established under Regulation (EEC) No 2309/93, Title IV, which is responsible for coordinating the existing scientific resources put at its disposal by the competent authorities of the Member States for the evaluation and supervision of medicinal products. Important functions are running the pharmacovigilance system and giving the best possible scientific advice on any question concerning the evaluation of the safety, quality or efficacy of medicinal products (Ibid, articles 20 and 51).

766 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

767 Chiti, op.cit.

768 Commission and Member State representatives take part at various levels, in informal contacts, in the Council, in Committees and expert groups, in both policy, legislative/political and operational contexts. Issues of duplication and efficiency arise here as well as flexibility.

769 For the reasons given above, this may entail an amendment to the Treaty.

770 R Dehousse, supra.

771 The Commission has been criticised for delay over the time to adopt (and invariably rubber-stamp) recommendations of the EMEA in the grant of marketing authorisations for medicinal products, but post-marketing decisions to suspend or withdraw products would be even more critical.

772 See ch 17.

773 R Van den Bergh, "The subsidiarity principle in European Community Law" *Maastricht Journal of European and Comparative Law* (1994) 1: 337-366 argues that competition between legislators will lead to legal systems competing against each other, to provide legislation that corresponds best to the preferences of citizens, although by 2003 it may be remarked that the speed of change and sheer number of legislative and implementational items on national agendas tends to preclude the ability to compare, reform and compete.

774 The Communication from the Commission to the European Parliament and the Council: Mutual recognition in the context of the follow-up to the Action Plan for the Single Market, COM (1999) 299, 16.6.1999 noted that mutual recognition was not operating satisfactorily, with problems most frequently reported in the foodstuffs, electrical engineering, motor vehicles, precious metals, construction and chemicals sectors. This

1990s of the decentralised system of marketing authorisations for medicinal products.[775] The Commission has itself concluded that mutual recognition works well for products that pose few safety problems (such as bicycles, tanks and containers), but has not worked well for technically more complex products (e.g. buses, lorries, construction products and precious metals) or products which can pose safety or health problems[776] (such as food supplements and fortified products).[777] One may therefore continue to observe the New Approach and the other product systems considered here with some sceptical interest.

Member States have ceded considerable control over policy in relation to the design of mechanisms for regulating product safety, through agreeing to pool their authority through the Treaty procedures, the qualified majority voting system, and comitology, plus decisions over pre-marketing authorisation.[778] On the other hand, each still remains almost solely responsible for the post-marketing aspects of market surveillance and enforcement mechanisms within its territory, and competent to make decisions on structure, resources, policy, specification of offences and institution of prosecutions, subject to the new obligations imposed by the GPSD and to being found in breach of Treaty obligations.[779]

Chapter 12 noted considerable variation between the Member States on market surveillance and enforcement issues, and continuance of disparities is one of the major threats to product safety, as well as to cohesion within the Union. Indeed, in the context of consumer product safety, the Economic and Social Committee has referred to a need to improve co-operation and information

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was echoed in the Council Resolution of 28 October 1999 on mutual recognition, 2000/C 141/02, OJ C 141/5, 19.5.2000. These comments were, of course, in areas covered either by New Approach legislation or no harmonized legislation. Similar problems arose in the more harmonized sector of medicinal products.

775 See chapter 4. The failure of mutual recognition in this sector was predicted by E Kaufer, "The Regulation of New Product Development in the Drug Industry" in G Majone (ed), *Deregulation or Reregulation? Regulatory Reform in Europe and the United States* (Pinter Publishers, 1990).

776 The Opinion of the Economic and Social Committee on "Mutual Recognition in the Single Market", 2001/C 116/03, PJ C 116/14, 20.4.1002, para 2.3.2 was that the greatest problems with mutual recognition occur in sectors with strong safety and health concerns and differing regulatory objectives between Member States

777 Report from the Commission to the Council, the European Parliament and the Economic and Social Committee: Second biennial Report on the Application of the Principle of Mutual Recognition in the Single Market, COM (2002) 419, 23.7.2002. The Commission concluded that the reason for failure lay with lack of familiarity of economic operators and national administrations with the principle: some. However, might consider that protectionism and an absence of persuasive sanctions may also have played a part. The Commission recognised that where sectoral national rules provide for significantly different levels of protection, the principle of mutual recognition cannot properly function, and legal harmonisation appears to be the most suitable solution.

778 Amongst a huge literature on this issue, see A McGee and S Weatherill, "The Evolution of the Single Market – Harmonisation or Liberalisation", [1990] *MLR* 53:5, 578.

779 See ch 12.

exchange among the EU enforcement bodies by, inter alia, developing a common approach to risk assessment based on objective and scientific criteria.[780]

Notified bodies

Notified bodies occupy the hybrid position of private commercial entities that are granted limited regulatory functions (for so long as they satisfy criteria), subject to scrutiny by competent authorities.

The involvement of a third party in the regulatory system should tend to reduce pressures towards capture, unless it is itself captured.[781] Recent experience[782] indicates some problems in practice with expertise and operation of the accountability process.

Standardisation bodies

The production of standards is an essential aspect of the New Approach and has been adopted also for consumer products. In delegating responsibility for production to the standardisation bodies, classic economic analysis predicts that issues arise of transparency, capture by industrial organisations with greater resources, and speed of production.[783] However, although the classic view is that regulatory capture is based on the notion that "private" influence over the regulatory process is illegitimate or detrimental,[784] it has been recognised that the system positively requires the active involvement of regulated firms in view of the necessity to include their technical expertise and practical knowledge.[785] The result is a system of *associative regulation.*[786] Empirical evidence is lacking that the undoubtedly strong involvement of industry, and weaker involvement of consumer

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780 Economic and Social Committee Opinion on "General Product Safety", 2000/C 51/16, OJ C 51/67, 23.2.2000, para 3.5.5.1.

781 This is similar to the concept of tripartism that was advocated by I Ayres and J Braithwaite, *Responsive Regulation* (Oxford, 1992). Their concept of Public Interest Group (PIG) involvement is not found in Community systems as a general rule, although arises as a long-stop mechanism of enforcement of consumer law under Directive on protection of consumer interests . The introduction of this mechanism constitutes a tentative trial to support enforcement in some Member States that do not have strong regulatory systems, but may be expected to be unpopular with effective regulators and regulates. A major objection to tripartism in which a PIG duplicates the role of regulators is excessive cost. As Ayres and Braithwaite suggest, contestable guardianship (under which the role of PIG has to be earned, awarded and may be removed) encourages competency and discourages capture, and contestability is indeed a feature of the notified body system.

782 See ch 5.

783 G Howells, op cit.

784 L Hancher and Moran, *Capitalism, Culture and Economic Regulation* (Oxford, 1989).

785 G Majone, *Regulating Europe* (Routledge, 1996); M Egan, supra, a detailed historical account of the development of standardisation.

786 M Egan, supra, referring to C Joerges, H Schepel and E Vos, "Delegation and the European Polity: The Law's Problem with the Role of Standardization Organizations in European Legislation", paper presented at the conference "Political Economy of Standards Setting", European University Institute, Florence, 4-5 June 1998.

representatives, in the production of standards has led to a safety deficit. It is not difficult to postulate industrial interest in seeking to influence standardisation so as to reduce the cost of compliance, but it is harder to support a case that such interest essentially supports lowering the safety barriers, especially given the overriding legal requirement that products be safe even if they comply with standards.[787]

Interest groups

Although the influence of economic operators can be criticised in regulatory theory, consultation with interested parties can both assist in overcoming democratic deficit and in informing the development of policy.[788] To what extent do interest groups exist? Some major trade associations and consumer organisations are at Table 10. On the industry side, the profile of large, medium and small sized producers varies between sectors. Some sectors such as pharmaceuticals, are characterised by, first, a relatively limited number of large multi-national research-based companies, that in recent years have been growing larger through merger and acquisition as a result of the increase in pressures and risk of financing the research and development of new products and, secondly, a number of companies that produce generic copies after new products lose patent protection.[789] The medical device sector has a small number of multi-nationals but a large number of small and medium sized companies. The motor-vehicle tobacco and cosmetics sectors are each dominated by a small number of multi-nationals but also populated with large numbers of smaller companies. Every sector has a trade association, whose functions include monitoring and lobbying a regulatory and standardisation issue, as do many sub-sectors.

The consumer side comprises some 500 million citizens of the EU for fewer organisations than the industry side, being focused on single national consumer organisations, in some states with particular-issue organisations, and a handful of organisations at national and Community level, each of whose functions include monitoring and lobbying on regulatory issues. Consumers have lobbied for greater involvement in standardisation work.[790] The power of consumer purchasing should not be underestimated.

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787 The involvement of larger firms in the process may also tend to introduce a raising of the requirements of standards for competitive reasons.

788 See ch 17.

789 A Towse (ed), *Industrial Policy and the Pharmaceutical Industry* (Office of Health Economics, 1995).

790 G Howells, *Consumer Product Safety* (Dartmouth, 1998).

It is not possible to state any empirical data on the activities or measure of success of influence exerted by individual companies, trade associations or consumer organisations, nor, thus, to compare their effectiveness. Anecdotal evidence claims victories and failures on both sides.[791] However, the Community has a rich and active consultation and lobbying system.[792]

Conclusions

Is the system likely to produce or enhance product safety? It has been seen both in this chapter and chapter 3 that the experience of the Community involves a close relationship between regulatory and trade policies.[793] A system of supranational governance involves complex and novel relationships and problems. In overview, one can see multiple actors amongst both regulators, regulated and those exposed to product risks. The existence of multiple actors complicates lines of communication, accountability and control, and raises the possibility of confusion, inconsistency, overlap and redundancy in the system. Accordingly, the finding that decisions on product safety are taken by different actors in different product sectors suggests scope for simplification and consistency across the sectors, which would bring improved clarity within a more unified system and greater consistency of decisions on risk.

The point can be illustrated by reference to the notification provisions in the 2001 GPSD that were identified in chapters 11 and 12. Notification of the existence of a dangerous product must be made not only by the producer but also by every distributor in the Community, and will involve multiple national regulators in different Member States. This will involve multiple channels of communication and potentially inconsistent responses. These findings suggest a need to rationalise communication channels and responsibility roles on both the commercial and regulators' sides. The evidence from chapter 12 indicates that there are significant problems in a number of respects on the regulators' side, such as the existing diffuse relationships involving national and Community-level market surveillance and enforcement authorities, and notified bodies. Rationalisation into a more cohesive mechanism is indicated.

Whilst mechanisms to increase the involvement of expertise have developed, concern remains in relation to the comitology structure and notified bodies over inadequacy of democratic

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791 Personal communications with various individuals.

792 S Mazey and J Richardson, "Institutionalizing Promiscuity: Commission-Interest Group Relations in the European Union" in A Stone Sweet, W Sandholtz and N Fligstein, *The Institutionalization of Europe* (Oxford, 2001).

793 M Egan, *Constructing a European Market* (Oxford, 2001).

accountability, control and due process, particularly in relation to post-marketing decisions on product safety. The problem is heightened by the fact that such decisions involve decisions on risk assessment that involve subjectivity as well as expertise, and therefore pose problems of integration of those two aspects. The argument that democratic deficit is reduced by the institutional balance provided by the unusual structure and interactions of the various entities[794] is not convincing in relation to product safety, where the requirements are not only for a high standard of scientific and technical decisions but also for the maintenance of public confidence through politically sensitive and speedy decisions on which opinions may differ.

These findings suggest that arguments for creation of a single Community Safety Agency[795] are compelling.[796] If this were to be created, there would be a need to balance accountability and judicial review mechanisms, the former through public scrutiny in a Parliamentary committee, plus a clear administrative appeal mechanism on substantive decisions in view of the abrogation by the courts of oversight on technical issues.

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794 K Lenaerts and A Verhoeven, "Institutional Balance as a Guarantee for Democracy in EU Governance" in C Joerges and R Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford, 2002).

795 The evidence and argument here concerns consumer products, but the same logic may well support the inclusion of workplace and hospital safety, and possibly environmental safety. It is relevant that the UK is merging a confusing number of safety data reporting systems within the health service into an integrated, rational system involving a smaller number of agencies, and may go further: *An organisation with a memory* (Department of Health, 2000); *Building a safer NHS for patients* (Department of Health, 2001).

796 I Ayres and J Braithwaite, *Response Regulation* (Oxford, 1992) argued for multiple-industry rather than single-agency jurisdiction coupled with rotating personnel for various reasons, including achieving effective enforcement on the "benign big gun" principle, reducing the risk of regulatory capture, increasing expertise and safety culture. There would also be the increase in scope to apply (horizontally) lessons from approaches taken in similar hazard or regulatory situations with dissimilar products: G Hayward, "Domestic and personal accidents: Prevention in the absence of professional supervision", *Accident Analysis and Prevention* 32 (2000) 329 at 332.

19. SAFETY AND RISK

Overview

Previous analysis has identified that the principal purpose of the product regulatory system is to ensure that a sufficient level of safety exists when products are used. The meaning of the concept of safety in relation to products is the focus of this chapter. It looks at the concepts of safety, risk, hazard, and risk assessment, how these are applied in product regulatory systems, and whether the legal tests are coherent.[797] It will be necessary to examine the issues from the different perspectives of legislator, regulator, producer and consumer. The starting-point is to examine the substantive legal tests that are currently specified in the legislation for placing products on the market or removing them from the market.[798]

The legal tests

The basic empirical observation from the existing legislation considered here[799] is that the legal tests that are set out for the various product sectors are different. This appears from the operative wording in Directives summarised in slightly abbreviated form at Table 1 and the wording of generalised essential requirements for New Approach Directives at Table 3.[800] Moreover, different tests apply for the same products within each sector that, firstly, the manufacturer must satisfy in order to justify placing a product on the market and, secondly, justifies the authorities in removing it from the market.[801] Each test relates, in some way, to ensuring human safety, but the wording differs, not only between sectors but also between the pre- and post-marketing situations. This lack of uniformity and coherence is striking.[802] Only the GPSD adopts the unequivocal test that products

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797 Examination of the philosophical validity of "safety" as an ethical or social policy is beyond the scope of this work, but the issues of acceptability and of Community policy are discussed below.

798 As discussed in ch 3, the legislation is constitutionally based on the creation and maintenance of a *market*, so the basic legal tests are applied to the placing of a product on, or removal from, the market. However, there are two exceptions. First, much New Approach legislation applies a secondary test at the point of "putting into service" in addition to or as an alternative for when it is placed on the market, essentially in order to cater for equipment that is constructed or finalised (eg calibrated) *in situ*. Secondly, Directive 2001/95/EC provides for controls at the point after a product has been "on the market" and has passed into consumers' ownership, namely in relation to the requirements mentioned above concerning taking appropriate action including recall.

799 The individual tests are set out in greater detail at ch 8.

800 New Approach Directives typically require that the product must comply with the essential requirements specified in Annex I when placed on the market.

801 The scheme of the legislation in the different sectors is similar in that the authorities are given a right to take action against a product that has been validly placed on the market. Only the GPSD (as revised from 2004) imposes an obligation on manufacturers and distributors to take appropriate action (as discussed in ch 6) where they have placed a dangerous product on the market: Directive 2001/95/EC, article 5.1. It is suggested that if such an obligation is appropriate for any product sector, it is appropriate for all sectors, and the legislation should be amended so as to conform in this respect. It should be noted that the authorities do have power to take action against dangerous products that, for example and as appropriate, have not undergone conformity assessment procedures, or do not comply with essential requirements, or do not have marketing authorisations.

802 It is not the function of this study to embark on an exhaustive analysis of the precise meaning and nuances of each form of words used, given the conclusion on the lack of uniformity. It has been pointed out at chs 4, 8, 11 and 12 that it is at

must be safe.[803] It is difficult to envisage a justification for differentiating in the legal test that should apply as between different product sectors.

It is also clear that the legislation recognises that at least the pre-marketing evaluation of safety takes place in the context of specific circumstances of use, which are usually to be defined in the labelling. Safety is here linked with requirements that the product must perform as intended (in New Approach terminology) or be efficacious in the approved indications (in medicines terminology).

The meaning of safety in the context of products

The tests quoted also differ in the wording and concepts used: some refer to safety as such but there is considerable variation overall. What is a safe product? McGee and Weatherill pointed in 1990 to a lack of understanding of what is meant by "safety" in Community legislation and acute divergence across the Community in perception of "reasonable safety".[804] The issue is further challenged by enlargement of the Union.

As recognised repeatedly above, there is no objective norm called "safety", nor an absolutely safe product, since safety is not a condition that is absolutely realisable in this world. However, public perception is frequently that regulated products are 100% safe.[805] There are degrees of safety: it is a relative concept,[806] which is imprecise and therefore poses difficulties as a legal test, although its lack of precision and empiricism makes it valuable in the context of political or media statements, which are by nature more generalised and qualitative. Accordingly, the level of safety that is desired or pertains in a given situation must always be assessed and considered in the light of a comparative assessment of benefits and risks in particular circumstances of use. Thus, the ISO/IEC Guide 51 on "Guidelines for the inclusion of safety aspects in standards" states:

> "Safety is a balance between freedom from risks of harm and other demands to be met by a product, process or service among which such items as utility, suitability for purpose, and the like are included.

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least curious that different tests are used for the two authorisation systems that apply to medicinal products. It should also be noted that different systems make differing (or no) provision in relation to obligations on manufacturers or powers of authorities to amend design, manufacturing, packaging or labelling aspects after a product type has first been marketed. One may wonder why identical, horizontal provisions do not apply: to some extent the GPS provisions provide for this, but not always.

803 Although, as discussed below, this concept is defined further, as minimal risks compatible with use.

804 A McGee and S Weatherill, "The Evolution of the Single Market – Harmonisation or Liberalisation", [1999] *MLR* 53:3, 578 at 586.

805 For example, a 2002 Mori poll found that 61% of the public questioned expected science to guarantee that a medicine is safe: *Safety, quality, efficacy: Report by the Comptroller and Auditor General* (National Audit Office, 2003), para 3.30. P Balen, 'Breast implants', *Clinical Risk* (2002) 8, 177-184 considered that "most consumers assume that the CE quality mark denotes government-approved safety".

806 *Reducing Risks, Protecting People*, Health and Safety Executive, 1999.

> There can be no absolute safety. Even at the highest level of safety, a product, process or service can only be relatively safe. The conventions of society, including levels of safety or degrees of risk, are subject to changes.
>
> .....
>
> As safety will pose different problems it is impossible to provide a set of precise provisions and recommendations that will apply in every case."

Despite references in recitals to basing decisions for medicinal products on safety,[807] the adoption in practice by regulators of a risk-benefit test,[808] has been approved by the courts:

> ".. [we] doubt whether much is to be gained by considering the meaning of the word 'safety' in isolation: indeed, I doubt whether it is possible to do so. Thus, a drug which creates few hazards if marketed with appropriate warnings and recommendations may be much more dangerous if these are omitted. Again, there is no absolute standard of safety. Very few drugs are entirely free from the risk of inducing adverse side effects in some patients. The question must always be whether the degree of risk is sufficiently low to be acceptable, and this cannot be addressed without an appreciation of the benefits to be gained from taking a risk of that degree.... I do not see how it can be decided whether the risk can now [once the drug has been marketed] be regarded as unacceptably great, without considering what level of risk should be treated as acceptable, in the light of the benefits to be gained from the marketing of the drug."[809]

Similarly, although the "general safety requirement" under the GPSD is that consumer products must be safe,[810] the definition of a legally safe consumer product is expanded to be one that has *minimum risks compatible with its use*.[811] This implies that a risk-benefit analysis should be undertaken.[812] But the problem is always that risk assessment, and risk-benefit assessment, involves making value judgments that are subjective. What risks constitute minimum risks, and what risks are compatible with use?

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807 Regulation (EEC) No 2309/93, recital 3; as discussed in chs 8 and 4, the legal tests for marketing and withdrawal of medicinal products differ between the centralised and mutual recognition systems, and between the marketing and withdrawal situations.

808 See chs 8, 17 and 4.

809 *Organon Laboratories Limited v Department of Health and Social Security* [1990] 2 CMLR 49, CA at 78 per Mustill LJ: the Court held that the licensing authority is entitled to take into account evidence of safety of a medicinal product in misuse, and comparisons of relative risks and benefits with other products.

810 Directive 2001/95/EC, article 3.1.

811 Directive 2001/95/EC, article 2(b), although this persists in including the unachievable and meaningless reference that a product shall have *no* risk. For more extended discussion see ch 8.

812 Although it seems that the Directive does not impose a legal requirement on the manufacturer to undertake such an assessment before marketing.

Risk and risk regulation

Risk is implicit in the marketing of products.[813] Some argue that we now live in a "risk society"[814] but others suggest that there are only different risk regimes.[815] The technical definition of risk given in the ISO/IEC Guide 51 is:

> "The probable rate of occurrence of a hazard causing harm and the degree of the severity of the harm."[816]

Risk, unlike safety, is capable of quantification and should be expressed as a percentage, and should be distinguished from "hazard",[817] but the term "risk" has become confused in common parlance with danger or hazard, and has been politicised.[818]

In recent years, understanding has emerged that regulation is a way of managing the risks associated with life in advanced societies,[819] involving incorporation of corporate risk management systems into the regulatory environment.[820] An extensive literature on risk has emerged,[821] in which analysis of

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813 In the area of product liability law, for example, in which commentary is perhaps more developed than product safety regulation, there is a large theoretical literature on economic effects: a summary is J Stapleton, *Product Liability* (Butterworths, 1994).

814 U Beck, *Risk Society: Towards a New Modernity* (Sage, 1992).

815 C Hood, H Rothstein and R Baldwin, *The Government of Risk* (Oxford, 2001), p 171.

816 Similarly, the definition of risk in ISO 8402 is "A combination of the probability, or frequency, of occurrence of a defined hazard and the magnitude of the consequences of the occurrence." and this is expanded as "the chance, in quantitative terms of a defined hazard occurring. It therefore combines a probabilistic measure of the occurrence of the primary event(s) with a measure of the consequences of that/those event(s). Criteria for acceptability of some predicted risk or measured risk can be set voluntarily by the organisation responsible and/or subjected to the hazard, or be set mandatorily by some regulatory organisation". Directive 96/82/EC on the control of major accident hazards involving dangerous substances similarly defines hazard as "the intrinsic property of a dangerous substance or physical situation, with a potential for creating damage to human health and/or the environment" and defines risk as "the likelihood of a specific effect occurring within a specified period or in specified circumstances". This Directive is one of those concerned with improved management of risks and prevention of accidents, and the limitation of their consequences, as part of environmental protection and of health and safety controls in the workplace. It includes a requirement for an accidental risk analysis. Operators are required to produce safety reports including their major accident prevention policy, safety management system, identification of major hazards, incorporation of adequate safety and reliability into their establishments, and emergency plans.

817 The ISO/IEC Guide 51 defines hazard as "A potential source of harm" and the definition in ISO 8402 refers to a situation or "the potential for adverse consequences of some primary event, sequence of events or combination of circumstances".

818 R Baldwin, C Scott and C Hood, *A Reader on Regulation* (Oxford, 1998), 35.

819 Royal Society, *Risk Assessment* (Royal Society, 1983); Royal Society, *Risk: Analysis, Perception, Management* (Royal Society, 1992); M Power, *The Audit Society* (Oxford, 1997).

820 The emerging literature relates to health and safety in the workplace, such as in manufacturing environments or railways: M Bovens, *The Quest for Responsibility: Accountability and Citizenship in Complex Organisations* (Cambridge, 1998); B M Hutter, *Regulation and Risk* (Oxford, 2001).

821 Summarised in R Baldwin and M Cave, *Understanding Regulation* (Oxford, 1999). For a spectrum see chapters by different authors in S Krimsky and D Golding (eds), *Social Theories of Risk* (Praeger, 1992).

risk is undertaken under different disciplines, such as behavioural/psychological science, culture,[822] social sciences,[823] business management,[824] and economics.[825] It has recently been argued that all theories may have some value in explaining how regimes are designed and operate, but to a differing extent.[826]

Whilst the conventional assumption is that the introduction of safety mechanisms through regulation will reduce risk, this effect may not occur because of behavioural compensation[827] or may even increase the danger of accidents "through a Titanic effect of perceived invulnerability (a placation process, encouraging a belief that nothing can possibly go wrong)".[828] The main regulatory challenges are[829] to identify those risks that need to be reduced as matters of priority, and to manage and regulate risks in an effective and acceptable manner.[830] Policy choices distinguish instruments that seek to modify the risk or to mitigate the effects of occurrence, depending on a judgment of whether prevention or promoting resilience is more achievable or effective. Serious problems plague the regulation of health risks.[831] Uncertainties surround[832] the value of cost-benefit analysis[833] and the extent to which experts should be involved in assessment or management of risk.[834] Ogus argues that a rational approach to social regulation requires the bifurcated approach of cost-benefit analysis of optimal care, followed by modification, taking into account differences between lay and

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822 M Douglas and A Wildavsky, *Risk and culture: an essay on the selection of technological and environmental dangers* (Berkeley: University of California Press, 1983); M Thompson, R Ellis, A Wildavsky, *Cultural theory* (Boulder, Colorado: Westview,1990).

823 The concept of a risk society has been discussed: U Beck, *Risk Society: Towards a New Modernity* (Sage, 1992); A Giddens, *Beyond Left and Right* (Cambridge, 1994); U Beck, 'The Politics of Risk Society' and A Giddens, 'Risk Society: The Context of British Politics', both in J Franklin (ed), *The Politics of Risk Society* (Cambridge, 1998).

824 For example, A Waring, *Safety Management Systems* (Chapman & Hall, 1996); J Bannister, *How to Manage Risk* (Lloyd's of London Press, 2ed, 1997); A Waring and A I Glendon, *Managing Risk* (International Thomson Business Press, 1998). One approach is to make organisations think like responsible individuals: C Stone, *Where the Law Ends: The Social Control of Corporate Behaviour* (Prospect Heights, Waveland Press, 1975).

825 Distribution of risk has always been central to insurance. Economic risk has also played a central part in the privatisation of the utilities and transport sectors.

826 C Hood, H Rothstein and R Baldwin, *The Government of Risk* (Oxford, 2001).

827 Such as driving a car or operating a machine in a reckless way because of the perception that it is safe/safer.

828 R Baldwin et al, op cit, 39.

829 R Baldwin and M Cave, op cit, 142-145.

830 C Hood and D Jones, *Accident and Design* (London, 1997).

831 S Breyer, *Breaking the Vicious Circle: Towards Effective Risk Regulation* ((Cambridge, Mass., 1993) identifies tunnel vision (producing over-regulation), random agenda selection (regulatory priorities driven by public attention) and inconsistency (differences of approach between agencies), for all of which frequent illustrations can be identified in the safety field. For recent attempts in the UK to improve performance in managing health risks, see *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer* (The Stationery Office, 2000), and *Building a safer NHS for patients: Implementing an organisation with a memory* (Department of Health, 2001).

832 J Adams, *Risk* (University College London, 1995) illuminates how different personality types approach measurement and expertise in risk taking.

833 K S Schrader-Frechette, *Risk and Rationality* (Berkeley, 1991).

834 There will usually be differences between the expert and public perceptions of risk, and of different hazards, and uncertainties over the reliability of available data, which lead to a breakdown in public confidence in regulatory institutions: S Breyer, op cit.

expert perceptions, to be undertaken by a body of experts independent of government, transparently and with public consultation.[835]

Risk-benefit and risk acceptability

It follows from the fact that risk, as defined above, is a concept that comprises the two aspects of *incidence* and the *severity* of particular hazards, and that risk should be expressed as a percentage, that decisions on the risks posed by products should logically be based on quantitative assessments of the incidence and severity of hazards. The process of identification of hazards and quantification of their risks, and the formation of a judgment on whether a particular risk is acceptable, is that of risk assessment. The quantification of incidence of particular hazards requires data to compare the frequency of occurrence of the hazard (numerator) against the total number of products in use (denominator).[836]

It follows that a risk-benefit test is imprecise as a legal test, unless there is confidence, first, that all relevant risks and benefits are included in the assessment,[837] and, secondly, that there are criteria against which a decision as to the acceptability of the resulting quantification can be made.[838] A test, such as that for consumer products, of the acceptability of minimum risks compatible with the product's use,[839] is satisfactory as a general principle[840] but ultimately unsatisfactory as a legal test since it permits subjectivity[841] and inconsistency.[842] The test for medicinal products of a favourable

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835 A Ogus, 'Risk Management and 'Rational' Social Regulation' in R Baldwin (ed), *Law and Uncertainty: Risks and Legal Processes* (Kluwer, 1997).

836 This arithmetic fraction is well-recognised in relation to medicinal products, and forms the basis of pharmacovigilance assessment. However, such data can be very difficult to access accurately for any product: the development of IT-based systems that would increase the accuracy of post-marketing safety decisions on both incidence (especially injuries compared with product use) and severity (of injuries, such as the EHLASS system was intended to provide) would significantly assist, but its utility should be measured against cost-effectiveness criteria.

837 Much Community legislation should score highly on this basis since, for example, extensive essential requirements are included in the Annexes to New Approach Directives, and their equivalent in prescribed or prohibited substances for cosmetics and biocides, tar and nicotine levels for cigarettes, and the seemingly exhaustive tests and clinical trials that are prescribed for medicinal products. Furthermore, such technical requirements have been extended historically, in accordance with the relatively unbureaucratic mechanisms to update them through advances in scientific and technical progress.

838 ISO/IEC Guide 51 distinguishes between risk evaluation (an empirical scientific activity, as defined above) and "judging safety" (assessing the acceptability of risks, associated with such factors as the socio-economic and educational background of the society concerned). Similarly, The Council for Science and Society, *The acceptability of risks* (London: Barry Rose, 1977), argued that the judgment of acceptability involves consideration of perceived costs and benefits in the light of feasible alternatives by the person exposed to the risk: ch 5.

839 The full text of this test is set out at ch 8: it states a number of particular considerations that are to be taken into account.

840 The similarity between the acceptability test for consumer product regulation and the liability test of "safety expectation" for compensation for damage caused by products specified in Directive 85/374/EEC, article 6, should be noted.

841 Subjectivity is recognised in the use of the concept of unacceptable risk under the construction products Directive 89/106/EEC. The Commission interpretation of the concept in this context includes: "Works (including their constituent installations and equipment) presents risks of accidents that are practically and economically impossible to eliminate completely...The acceptability of a risk is estimated by considering the seriousness of the accident, the probability of its occurrence and the possibility of recourse to technically and

risk-benefit balance is perhaps the most sophisticated test that is currently adopted but begs all the issues as to which acceptability criteria are to be applied and is in operation either untransparent (because subject to complex expert determination) or in extreme cases subject to the arbitrary, blunt intervention of political influence. A lack of clarity over such important tests may lead to confusion and conflict between producers, regulators and consumers, to inconsistency of individual decisions (and there are so many individual decisions on product risk), and it may ultimately undermine confidence in the legal system. On this basis, all of the Community legislation considered here is lacking in failing to adopt a coherent test for the basis of pre- or post-marketing decisions on product safety, in particular in the absence of risk-acceptability criteria. Two broad historical trends can be distinguished: sectoral legislation been based around specification of technical requirements (i.e. identification of potential hazards) whereas the horizontal GPS provisions of the 1990s are based on the more fundamental but generalised and political criterion of "safe product", defined in "minimum risk" terms, but in both cases without risk-acceptability criteria. A major conclusion of this thesis is the need to develop such criteria.

Risk assessment and management for the different actors

Legislators, manufacturers (or other economic operators), regulators, courts[843] and consumers/users should all apply risk assessment and management processes, albeit to differing degrees:[844] there has been much development in the identification and definition of such processes.[845] These different actors have differing approaches.

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economically reasonable preventive measures." Communication from the Commission with regard to the interpretative documents of Council Directive 89/106/EEC, OJ C 62/1, 28.2.94 at C 62/109.

842 P Cartwright, "The Regulation of Product Safety" in G Howells (ed), *The Law of Product Liability* (Butterworths, 2000) argues that the test is paternalistic. In fact, The Commission believed that the concept of risk was "sufficiently flexible to cover any product, without unreasonably restricting its marketing and further development - including those products which are said to bear an 'inherent' risk": Explanatory Note, COM (89) 162/6. It is surprising that such a fundamental concept as that of risk is not defined in the Directive.

843 It can be argued that courts, who may be called upon to make final decisions on the legal interpretation of tests of the regulatory compliance of products with safety/risk tests have appropriate expertise in interpreting tests that are broadly formulated, yet even judges may reach different decisions on such broad wording and their decisions may differ from those of other actors. It is also true that there is a very wide range of products, that given risk to a spectrum of safety issues that need to be evaluated, and that this makes it difficult to specify generalised tests.

844 States who are members of the World Trade Organisation are obliged to ensure that their sanitary and phytosanitary measures are based on risk assessment: Agreement on the Application of Sanitary and Phytosanitary Measures, article 5.

845 Major evolutions were the British standard BS 5750 in 1979 and its international adoption as ISO 9000 in 1994, revised in 2000.

Legislators and regulators

The concerns of legislators and regulators begin with macro-effects on their populations,[846] in trying to identify unreasonable risks in order that remedial or legislative action can be taken. Such analysis involves risk assessment[847] and then cost-benefit analysis,[848] although there is little evidence that such analyses are actually carried out.[849] Data on incidence of hazards should be collected and adjusted to take account of the level of actual use, changes in the amount of use, and as wide a range of comparisons between product types as possible.[850] Economic analysis of this kind is not without serious difficulties,[851] not least over ethical and computational difficulties in ascribing value to both human life and injuries, although this is not an impossible exercise.[852] The allocation of monetary value to aspects human safety is in fact required in order to assess the efficiency and comparative effectiveness of different measures.

It is implicit that an "impersonal" economics-based approach may tolerate a certain level of injury to the population at large, which can be justified on the basis that the costs of regulation exceed the costs of benefits obtained. However, macro-decisions are also susceptible to cost-benefit decision

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846 The Community has recently firmly stated that theory distinguishes risk assessment (which it defines as a scientific task carried out by experts and regulators) from risk management (which involves policy choices and, it asserts, remains in the hands of the Commission) in relation to regulation of risks with food: Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety, COM(00)716, 8.11.2000, at 13-14. See R Dehousse, 'Misfits: EU Law and the Transformation of European Governance', in C Joerges and R Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford, 2002).

847 Various experts have argued that the primary criterion for the setting of priorities in product safety regulation should be the probability of injury. However, data simply on the total number of injuries or adverse events is inadequate for risk assessment purposes unless the requirement is for absolute safety, i.e. a total absence of injury. W K Viscusi, *Regulating Consumer Product Safety* (American Enterprise Institute for Public Policy Research, 1984). G Hayward, 'Risk of Injury per Hour of Exposure to Consumer Products', *Accid. Anal. and Prev.* 28 (1996), 115. Both of these sources provide comparative statistics and charts from which conclusions can be drawn, such as Hayward's on perceived risk/accident risk per million hours of exposure, and on total medical costs per million adults per year/accident risk per million hours of exposure. The Commission accepts that risk analysis should be a requirement for proposals concerning hazards and risks: Enterprise Working Paper: Business Impact Assessment Pilot Project, Final Report: Lessons learned and the way forward (2002).

848 See R Sugden and A Williams, *The principles of practical cost-benefit analysis* (Oxford, 1978). Theory on decisions to introduce regulation on the basis of market failure to deliver acceptable levels of safety, and factors affecting enforcement policy, are discussed in ch 17.

849 Viscusi, supra, found that the US authorities usually omitted benefit-cost and cost-effectiveness tests (p 101), and also that the Consumer Product Safety Commission had an effect on safety that was so small that one could not be confident that it differed from zero (p 73).

850 *Data Collection Systems related to Injuries involving Consumer Products* (OECD, 1978); *Severity Weighting of Data on Accidents involving Consumer Products* (OECD, 1979).

851 The Commission claimed that carrying out a proper cost-benefit analysis of the draft recast Directive on machinery was virtually impossible given the variety of possible situations: Proposal for a Directive COM(2000) 899, 26.1.2001, Explanatory memorandum para 11.

852 A report for the UK Department of Trade and Industry that considered valuation of a statistical life noted significant uncertainties associated with all methods of injury valuation: *The Optimisation of Consumer Safety* (Middlesex University, 1998). It also recognised that while the use of cost-benefit analysis in safety decisions can provide valuable assistance to decision makers, it is based upon the particular philosophy of utilitarianism which is not necessarily the best arbiter for all consumer issues.

in political terms, where public pressure based on the public perception of an adverse balance, or excessive risks, can lead to reduction in tolerance of incidence of death or injury.[853] The issue here is to ask by how much injuries and deaths would be reduced as a result of the measure, or, if a product is removed from the market, what would be the safety effect of those that remain on the market, given compensating behaviour by consumers? Will the risk in fact be reduced to an acceptable level?[854]

Breyer notes that regulators who undertake risk management can suffer from various problems, notably tunnel vision (concentration on achieving a disproportionately costly and unnecessarily high level of compliance), random selection of agendas and priorities, and inconsistency (such as between different agencies over methodology for estimation of the effects of regulation, or over their cost-benefit evaluations or understanding of the combined effects of regulation): significantly, he argues for the creation of a unified regulatory structure with a specific risk-related mission (building an improved, coherent risk-regulating system, rather than the achievement of zero risk in specific instances[855]), which would involve comparing programmes so as to achieve a prioritised allocation of resources, and the ability to share experience across related areas.[856]

Manufacturers

The application of risk management to the commercial processes, such as design,[857] manufacturing, distribution[858] and in the post-marketing phase, seeks to prevent or reduce risk through requiring producers to undertake procedures designed to identify, assess and manage risks, and is now widely practised by major companies.[859] Yet the legislation governing almost every sector includes no legal requirement to undertake formal, documented risk assessments,[860] even though a risk assessment

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853 Discussed further below.

854 It should, however, also be considered whether the reduction of an individual risk beyond a certain point will in fact benefit society, perhaps because this will involve excessive cost in relation to the benefit, or because the individual action becomes a disproportionate priority (tunnel vision by regulators): S Breyer, *Breaking the Vicious Circle* (Harvard, 1993).

855 Breyer argues that the individualised tunnel vision produced by a plethora of regulatory agencies produces little understanding of the effects of individual measures and policies in real life, and that comparative analysis, particularly of comparative behavioural effects, can show, in stark terms, that some actions can kill more people than are saved.

856 S Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Harvard, 1993).

857 BS 7000 Design management systems.

858 ISO 10005:1995 Quality management – Guidelines for quality plans.

859 Nevertheless, a survey of companies involved in product recalls in USA concluded that (a) there is currently no standard industry approach to proactively managing product safety during product development, but wide variation in practices, (b) there was a strong correlation between Product Stewardship best practices and safety record, although only 20% of the companies surveyed managed safety issues well, with a full but costly complement of Product Stewardship practices, but these were able to use their safety record to competitive advantage: T White and R Pomponi, *Gaining a Competitive Advantage by Building Safety into Your Products* (PRTM, 2002).

860 Risk assessment is explicit for biocides (Directive 98/8/EEC, Annex VI) and machinery: Directive 98/37/EC, Annex I, para 3 states that the manufacturer is under an obligation to assess the hazards in order to identify all of those which apply to his machine, and then design and construct it taking account of his assessment. Standard EN 1050 'Safety of

standard for manufacturers was recommended by OECD as long ago as 1979[861] and both the basic methodology plus a simple risk level indicator and risk-based control plan, which could form the basis of any general framework, are stated in the British standard Guide on Occupational Health and Safety Management Systems.[862] It is difficult to see how a manufacturer could logically satisfy the requirement that consumer products must have only minimum risks compatible with use unless he undertakes and updates a documented risk assessment, and there appears to be a strong case for amending introducing such a requirement into the legislation.

Consumers

The risk assessments that are undertaken by individual consumers are usually brief and impulsive rather than computed or comprehensive before using products.[863] Issues arise of basic intelligence, comprehension, evaluation, perception, behavioural traits, and personal choice as to acceptability, even given perfect information. Differing political approaches are also relevant: liberalism favours personal choice to take risks whereas paternalism is more interventionalist and assumes a lower acceptability of risks.

Difficulties with the available statistics

The only systematic attempts to collect data on product safety are the EHLASS system for consumer products (now discontinued), and the pharmacovigilance and medical device vigilance systems. There are inadequacies with each of these systems, particularly over identifying the number of products in circulation (denominator), the number that give rise to safety concerns (incidence - numerator), and the severity of individual hazards.

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machinery – Principles for risk assessment' is intended to assist with this. Risk assessment is also implicit for medical devices and pressure equipment by inclusion in the essential requirements, although its enforceability is uncertain since the primary obligation is that the product must meet/comply with the essential requirements when placed on the market, and this arguably fails to impose an obligation specifically to undertake a risk assessment. For medical devices, Directive 93/42/EEC, Annex I, para 2 specifies that the manufacturer must apply the principles of risk elimination or reduction, taking adequate protection measures for risks that cannot be eliminated, and inform users of residual risks. Standard EN ISO 14971:2001 'Medical devices – Application of risk management to medical devices' is available. Note criticism of the previous standard: H Atchia, 'EN 1441 – A Standard in need of urgent re-think?', *The Regulatory Affairs Journal (Devices)*, August 1998, 181. The medicinal product system implies risk assessment of the results of tests carried out. It is an essential requirement for lifts (Directive 95/16/EC) to assess the hazards, but there is no mention of then reducing them! It is curious that requirements or standards for risk assessment are not more widespread.

861 Recommendation of the Council Concerning the Safety of Consumer Products, OECD, C(79)202, 1 December 1979.

862 BS 8800:1996.

863 This may be the general position for use of most consumer products, since they are perceived to be "safe", but it does not always apply. For example, patients with particular diseases can be well-informed as to the comparative risks and benefits of their condition and possible treatment options, and carry out sophisticated risk assessments.

An attempt has been made to collate available statistics, mainly from national sources, in Appendices 2 - 4 in relation to the incidence and/or severity of adverse safety events. It is impossible to conclude, on any objective basis, whether the levels of safety represented by these data are or are not acceptable, given the absence of risk-acceptability criteria. Any views that might be expressed on such acceptability would be purely subjective. It is, however, apparent that the level of safety that is accepted for different products varies. This begs the question of whether it is acceptable social policy for different levels of safety to be acceptable for different products, or whether there should be an uniform approach: if the former, should there not be a rationally integrated approach, on the basis of a reasoned, statistical matrix, even if individual figures within that matrix vary at different points in time? Alternatively, is this taking an empirical approach to the issue of safety too far? These are philosophical points that are outside the scope of this study, but which this study clearly identifies are requiring answers if the regulation of product safety is to be coherent.

It is also apparent from the data that are assembled in the Appendices that there is little[864] or no systematic attempt to collect safety data which could form the basis of evaluation of:

- the prevailing level of safety of products;
- the efficiency of the regulatory systems or of particular measures;
- whether a particular measure is justified on a cost/benefit test, such that the marginal increase in safety that it produces can be compared with the marginal increase in cost;
- whether particular initiatives should be launched or are successful.[865]

Perception and acceptability of risks

ECOSA has noted a fundamental misconception in society about risks, suggesting that people attribute more value to reducing risks that are (1) involuntary, (2) poorly understood,[866] (3) potentially catastrophic, and (4) hard to control in the case of an outbreak.[867] This explains much greater interest in controlling food safety, nuclear safety and transport safety, and a lower priority attributed to home safety, sports and reaction and safety at school. Similarly, a former Chief

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864 The pharmacovigilance system and to some extent the medical device vigilance system are the most advanced in data collection, but there are gaps and issues of transparency.

865 Statistics that over 60,000 people a year receive hospital treatment in the UK for packaging accidents (2% of home accidents), costing the health service over £12 million, were used to justify a research project to help designers produce better packaging: DTI press release, 26 March 2001.

866 G Hayward, 'Risk of injury per hour of exposure to consumer products' *Accid.Anal. and Prev.* 28 (1996) 115, found that people rely over-much on constructs of sharpness and power of products in their perception of danger, rather than an assessment of the situations that can arise during use of the products, and the likelihood of them doing so. Hayward concluded that there is a need for objective criteria for setting priorities.

867 *Priorities for Consumer Safety in the European Union: Agenda for Action*, (European Consumer Safety Association, 2001).

Medical Officer for England and Wales expressed concern that the public perception of risk of adverse drug reactions was not consistent with other kinds of risk to which people are exposed on a daily basis.[868] It would seem that most people are content to accept what is quantifiable as a 1 in 10,000 chance of death from a road traffic accident in a single year without great concern, yet media reports of individual drug risks or disasters generate levels of concern that seem illogical when the statistics are viewed objectively.[869] However, in some contexts the public can ignore the significance of safety information.[870]

The incidence of death and injuries can vary over time, and both public perception and policy are certainly open to change.[871] The general perception is that levels of safety have risen for consumer products generally in recent decades,[872] and should be high, but individual issues threaten this, particularly if they are sudden.[873] Equally, consumer pressure can have an effect on commercial activity and industry's view of acceptability.[874] The fact that particular commercial manufacturers or suppliers have high reputations for quality clearly influences consumers' perceptions over the safety of their products, and is a well-recognised mechanism of self-regulation in markets.[875]

Key research findings are that individuals' perception of comparative danger of products is an unreliable guide to the actual risk of injury of a product in use[876] and that public and expert

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868 K C Calman and H D Royston, "Risk language and dialects", *BMJ*, 1997;**315**:939-42.

869 I Hargreaves, J Lewis, T Speers, *Towards a better map: Science, the public and the media* (Economic and Social Research Council, 2003).

870 'Cancer link to fried food fails to check British appetite for chips', *Sunday Telegraph*, May 2002. See further ch 10.

871 It has been said that improved prosperity and standards of living over the last century have lead to an apparent aspiration for a society free of involuntary risks, underpinned by a belief that the state has a duty to insulate people from harm: J Le Guen, *Reducing Risks, Protecting People* Health and Safety Executive, 1999.

872 See n 30 above and Opinion of the Economic and Social Committee on 'General Product Safety' 2000/C 51/16, OJ C 51/67, 23.2.2000, which held that standards have steadily improved. *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001) stated that in Europe, deaths in the workplace fell 14% between 1994 and 1996, deaths on the road fell 27% and traffic injuries fell 11% between 1980 and 1995 despite a 50% increase in traffic volumes in that period.

873 Ogus, supra, 75, notes that swift responses to problems that suddenly receive prominent media attention can lead to over-regulation. Generalised release of information by the media outstrips dissemination of detailed data to professionals such as doctors, and this can increase public anxiety: N Kirkpatrick and B Jones, 'The TrilucentTM breast implant experience', *Clinical Risk* (2003) **9**, 1-9.

874 Threatened boycott of the products of Hoechst Inc led it to abandon its involvement in developing the anti-abortion pill RU486 after it concluded that it "could not take the risk": A Jack, B Clark and D Green, "Boycott forces Hoechst to drop abortion pill", *Financial Times*, 9 April 1997.

875 See examples cited in J Kay and J Vickers, "Regulatory Reform: An Appraisal" in G Majone, *Deregulation or Re-regulation? Regulatory Reform in Europe and the United States* (Pinter Publishers, 1990).

876 G Hayward, 'Risk of Injury per hour of exposure to consumer products' (1996) *Accid. Anal. and Prev.*, 28/1, 115-121. This was a study carried out by the Consumer Safety Unit of the Department of Trade and Industry in 1993. It found that people over-rely on constructs of sharpness and power of products in their perception of danger, rather than an assessment of the situations that can arise during their use and the likelihood of them doing so. Leonard and Wogalter found that adults were often aware of a substantial number of hazards, but their knowledge did not extend to the specific circumstances that could produce personal injury: *Accid. Anal. and Prev.*(2000) 32, 3.

perception also differs.[877] Public policy and regulators will primarily be concerned with the actual risk,[878] but individuals will be influenced by their personal perceptions, mental ability and personality types in taking risk decisions.[879] The co-existence of these differences therefore creates difficulties in setting safety and regulatory priorities. This disconnect between public and scientific perceptions of risk and, with the further involvement of the media[880] and politicians, has led to issues of confidence in regulatory systems and calls for greater transparency in decision-making and for greater consumer involvement,[881] thus underlining the importance of bridging deficits in democratic accountability.

Various conclusions flow from the finding that risk assessment and management decisions necessarily involve subjectivity in judging whether risks have been reduced to acceptable levels,[882] and that there will be differences in risk decisions by regulators and producers (which may entail determinations by experts, civil servants, politicians or consumers that may differ both between themselves and from the perception of individual consumers and public perception) and by consumers. There needs to be, first, transparency over risk assessment processes (methodology, values used, and results obtained),[883] secondly, consensus as to the value judgment of the acceptability of the computed results as against socio-political criteria,[884] thirdly, effort needs to be expended on improving public perception of actual risk and in adopting appropriately responsible

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877 S Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Harvard, 1993) demonstrates that the public's (ie individuals') perception of risk differs widely from any consensus of experts in the field, and that a vicious circle is created, diminishing public trust in regulatory institutions and inhibiting more rational regulation.

878 Although not always satisfactorily: It has been said that awareness of adverse drug reactions, as a major problem in the treatment of most diseases, by doctors, patients, pharmaceutical companies and national regulatory agencies has had little effect in improving safety evaluation over the past 20-30 years: A P Fletcher and S Shaw, "The safety of medicines" in JP Griffin, *op cit.*

879 R G Noll and J E Krier, 'Some implications of cognitive psychology for risk regulation' (1990) 19 *J Legal Stud* 747. G Hayward, 'Introduction: Domestic and personal accidents. Prevention in the absence of professional supervision' in *Accid. Anal. and Prev* (2000) 32: 329-335 referred to the very heterogeneous cross-section of humanity, from the very experienced to the dangerously naïve, from the reluctant and disinterested to the over-enthusiastic and over-confident, from the very young to the very old.

880 R E Kasperson, O Renn, P Slovic et al, 'The social amplification of risk: A conceptual framework' *Risk Analysis* (1988) 8(2), 177-187 agues that the impact of a particular risk begins with the initial victims and diffuses outwards to society at large, thus public response to risks can be amplified or attenuated depending on how its reporting interacts with psychological, social, cultural and institutional processes. A Maxwell, 'Public perception and politics drive EU medical device regulation', *Clinica* 952 (2001) April 2, p4.

881 A Ogus, 'Risk Management and 'Rational' Social Regulation' in R Baldwin (ed), *Law and Uncertainty: Risks and Legal Process* (Kluwer, 1997).

882 The basic risk assessment methodology, as set out, for example, in BS 8800:1996 referred to above, merely requires a decision as to whether the risk is *tolerable*, without further guidance on how that is to be *judged*.

883 Lord Phillips of Worth Matravers concluded in *Report, evidence and supporting papers of the Inquiry into the emergence and identification of Bovine Spongiform Encephalopathy (BSE) and variant Creutzfeldt-Jacob Disease (vCJD) and the action taken in response to it up to 20 march 1996* (The Stationey Office, 2000) that fear of engendering public panic is never a reason to conceal information on risk.

884 The concept of "tolerability" is becoming used in professional circles, although this still involves subjective judgment. It should be noted that the 2001 GPSD uses the higher, but undefined, trigger of "serious risk" for rapid action: ITS Research and Testing Centre were requested to define this concept and their work has built on the risk estimator of BS 8800, but is still very conceptual and difficult to apply in practice or consistently across different product types and situations.

behaviour in product use,[885] and fourthly, scientific evaluation of risk has value, and effort should be expended towards obtaining reliable data and its evaluation and use, although the limitations in use of the scientific approach must be recognised given the public perception disconnect.

Politics and consumer confidence

The fact that personal and public perceptions of the safety of individual products and of the reliability of safety regulation are significantly influenced by confidence in the system,[886] and that issues of confidence require political solutions that include aspects of public acceptability, can be illustrated by some examples. These also illustrate findings that the news media play a clear role in how people understand science, and that public awareness is largely limited to the main themes or frameworks rather than an understanding or retention of factual material, and is often influenced by repeated associations.[887]

The impact of the BSE issue on the food industry.

Five particular issues arose in the BSE saga: first the effectiveness of the authorities' surveillance and enforcement of producers' activities in order to control breaches of requirements (the accurate and sufficient removal of spinal materials from beef carcasses);[888] secondly, the accurate assessment of risk by the scientific authorities; thirdly, the making public of full and accurate information on risk; fourthly, whether the political and regulatory authorities adopted the correct approach to regulating the safety of food products; and, fifthly, the coherence of the inter-relation of poor governmental communications with media's commercial priorities in triggering public alarm.[889]

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885 ECOSA state that accident analysis and research evidence suggest that over 80% of accidents are preventable and that a reduction in incidence of accidents in Europe should be a realistic target for the next twenty years: *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001). ECOSA asserts that "interventions are proven to be effective" citing examples of the introduction of child-resistant packaging for poisonous products that reduced deaths by poisoning by 38%, and use of bicycle helmets reducing head injuries by 85% and brain injury by 88%: Harbour View Injury Prevention and Research Centre/Cochrane Collaboration, University of Washington, Seattle, 2000, cited in ECOSA, supra. A valiant attempt in public education on a broad range of risks encountered in life is *Living with Risk: The British Medical Association Guide* (John Wiley & Sons, 1987).

886 There are various references in Community documents to the importance of maintaining consumer confidence in the internal market, such as Opinion of the Economic and Social Committee on 'Use of the precautionary principle', 2000/C 268/04, OJ C268/6, 19.9.2000. See also Regulation 2560/01 to maintaining confidence in the Euro and Directive 99/44/EC on certain aspects of the sale of consumer goods and associated guarantees to "whereas the creation of a common set of minimum rules of consumer law, valid no matter where goods are purchased within the Community, will strengthen consumer confidence and enable consumers to make the most of the internal market ...": see discussion in S Weatherill "The Commission's Options for Developing EC Consumer Protection and Contract Law: Assessing the Constitutional Basis" [2002] EBLR 497, 511.

887 I Hargreaves, J Lewis, T Speers, *Towards a better map: Science, the public and the media* (Economic and Social Research Council, 2003).

888 "Recent food safety crises have highlighted deficiencies in national systems of control." Commission of the European Communities, *White Paper on Food Safety* COM (1999) 719 final, 12 January 2000.

889 S C Ratzan (ed), *The Mad Cow Crisis: Health and the Public Good* (New York University Press, 1998).

Together, these issues dominated the Community's approach to safety issues for most of the 1990s[890] and led to a complete reassessment of the foodstuffs regulatory system and total recasting of its legislation. The fourth issue led to the development of a new approach to post-marketing surveillance and product safety, the precautionary principle.[891]

The Commission said in its 2001 White Paper on European Governance[892] that many people were losing confidence in a poorly understood and complex system to deliver the policies that they want, and gave concerns over food safety as an example of a perceived inability of the Union to act effectively where a clear case exists, noting also the resulting issue of alienation. The Commission concluded that "The Union's credibility will eventually be judged by its ability to add value to national policies and address people's concerns more effectively at European and global level."[893]

Similarly, in the context of revision the GPSD, it was said in 2000 that

> "It must also be made quite clear that acceptability of the risk factor depends on the attitudes of society towards the minimum unavoidable risks people are prepared to tolerate. It must also be apparent that society progressively raises its standards towards the risks it will tolerate".[894]

The "pill scare"[895]

In 1995 the United Kingdom's Committee on Safety of Medicines issued advice to prescribers, based on data from uncompleted clinical trials, that the "third generation" of oral contraceptive products was twice as likely to cause deep vein thrombosis (DVT) as "second generation" products.[896] This resulted in "a long-term crisis of confidence in oral contraception... [and] led to the highest level yet of legal abortions", rising from 8 per 1,000 in 1971 to 14 per 1,000 in 1988, an estimated extra 29,000 abortions, and an apology in 1999 by the Department of Health.[897] However, although the risk of DVT for third generation products (25 per 100,000 women per year) was larger

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890 Even Directive 85/374/EEC on product liability was amended by Directive 1999/34/EC so as to remove the optional exclusion of producers of primary agricultural products and game, at the request of the European Parliament.

891 Noted at ch 12.

892 *European Governance: A White Paper* 2001/C 287/01, OJ No C 287/1, 12.10.2001. It had been said in Decision No 283/1999/EC of the European Parliament and of the Council of 25 January 1999 establishing a general framework for Community activities in favour of consumers, OJ L 34/1, 9.2.1999, that the Council "recognises that everything must be done to restore public confidence, severely shaken by the BSE crisis".

893 Ibid.

894 Economic and Social Committee Opinion on "General Product Safety" 2000/C 51/16, OJ No C 51/67, 23.2.2000, para 3.2.2.5.

895 *XYZ and others v Schering Health Care Limited and others* [2002] EWHC 1420 (QB) per Mackay J.

896 It was said in *Health Services: Arrangements for Dealing with Major Incidents* ID 98C 173/235, Nov. 1998 that "These risks were small, much less than the risks of unwanted pregnancy, but the media published a 'scare story'".

897 L Jury "Pill scare drives abortions to record", *Independent*, 17 February 1999. C Hall, "Health chiefs sorry for rise in abortions caused by pill scare", *Daily Telegraph*, 8 April 1999.

then for second generation products (15 per 100,000 women per year) still less than the incidence during pregnancy (60 per 100,000 pregnancies), as against 5 per 100,000 for women not taking the pill. The manufacturers' appeal to the CSM was rejected but their appeal to the Medicines Commission led to revised advice and product information being issued,[898] which continued public and professional questioning on confidence in the system.[899] Product liability claims by users against the manufacturers (but not the authorities) were dismissed.[900]

There are several interesting lessons from this case. The CSM was rightly concerned to discharge its function of ensuring public health by issuing new and accurate information as swiftly as possible to prescribers and thence to users. However, the outcome was that the media interpreted the significance of the new information differently when it was first issued and when finally revised, because it was ultimately placed in a wider and different context after more time had been taken to review the entirety of the data. Thus, lessons include that time for expert evaluation of data is useful; and therefore that the immediate transparency of safety information may not be advisable in cases where it needs to be evaluated and put in context by experts, particularly in instances where the media may misinterpret its significance. These points do not alter the principle that there should be public and timely disclosure of accurate safety information.

The breadth of types of risk

It is useful to remember that the number and range of products that are covered by regulation is enormous, and this makes generalisation difficult. It encompasses, for example, cotton buds, toys, electrical equipment, lifts, machines, pace-makers, cars, cosmetics, detergents, medicines and so on. Some are used by consumers, others in the workplace, and some by both. The range of hazards and the magnitude of the risks that arise vary enormously. Although different regulatory systems have evolved for particular product types, there is considerable overlap between the basic principles and the regulatory mechanisms that do and should apply.

The type of risk that may or does arise affects the context of the regulatory regime, and public perception.[901] Relevant issues are: what is the source or cause, how familiar and well-established it is, how easily it can be quantified, how suddenly it may occur, what severity and incidence of

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898 The revenue loss to the manufacturers was estimated at £70 million: L McKee and M Verrall, "Drug firms threaten legal action", *Pulse*, 17 April 1999.

899 "The fiasco over third-generation oral contraceptives will do little to bolster GPs' confidence in the advice they receive on the safety of medicines...GPs will wonder how such different conclusions can come from the same data." Anon, "Medicines advice must be reliable", *Doctor*, 15 April 1999.

900 C Dyer, 'Judge rejects claims of birth pill health risk', *The Guardian*, 30 July 2002.

901 C Hood, H Rothstein and R Baldwin, *The Government of Risk* (Oxford, 2001), p 28.

consequences it may have, with what probability it may occur? These variables illuminate to some extent differences in the types of regime that apply to different products. For example, some products may present catastrophic risks of sudden death in large numbers have become feared from certain aspects of post-modern life,[902] although the risks from others are small and predictable. The need for a range of regulatory techniques is, therefore, to be predicted.

Community policy on consumer safety and social protection

It has been argued above that there is a need for a society to reach consensus on its criteria for judging the acceptability of risk, and that if this matter is left in the hands of experts or those who are required to make decisions, tensions will arise. What is Community policy on such criteria? There is no identifiable consensus on risk-acceptability criteria. The analysis of Community policy at chapter 3 reveals merely that product safety regulation must "take as a base level a high level of protection" of health and safety. As we have seen, this phrase is aspirational and political but largely meaningless, and of no use in measuring whether individual regulatory mechanisms or measures, still less individual products, comply with the test. Individual Member States are still permitted to set their own policies on health and safety issues, even where these constitute barriers to internal trade, as long as they fall within the exemption of protection of health and life provided for in Article 30 EC and satisfy the principle of proportionality: the system leaves Member States considerable discretion in setting individual levels of protection.

A Community policy on consumer protection has existed since 1975[903] and successive three-year plans have supported the sectoral and horizontal legislation considered here, based on the policy of a high level of protection of health and safety, discussed in chapter 3. In this context, it will be seen that "a high level of protection" is meaningless in establishing criteria.

The current consumer protection policy states:[904]

> "EU consumer policy should provide essential health and safety requirements and safeguard economic interests to ensure a high level of protection and meet the expectations of citizens throughout the EU. Products and services placed on the market should be safe

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902 Asbestos, viruses such as HIV, BSE/vCJD, Hepatitis C, genetic manipulation, electromagnetic field effects.

903 See C Hodges " Product safety in Community consumer protection policy" in C Hodges, M Tyler and H Abbott, *Product Safety* (Sweet & Maxwell, 1996).

904 Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions: Consumer Policy Strategy 2002-2006, COM (2002) 208 final, 7.5.2002. This policy is supported in Decision No 283/1999/EC of the European Parliament and of the Council of 25 January 1999 establishing a general framework for Community activities in favour of consumers, OJ L 34/1, 9.2.1999. Safety is also included in *Guidelines for Consumer Protection* (United Nations Department of International Economic and Social Affairs, 1986).

and consumers should receive the relevant information to make appropriate choices.... Much of the work in this domain concerns legislation and other actions having a direct impact on market behaviour, such as standardisation, codes of conduct or best practice."

This policy clearly places safety as a fundamental goal, although the formulation seems to indicate the political formulation of an expectation of absolute safety, which is an unachievable goal. Some have argued that there should be a human right of consumers to safety.[905] It appears that there is public support for the results of the prevailing approach to consumer protection, even though individuals may be ignorant that there is a formal policy.[906] Consumers also believe that standards vary across Member States.[907]

Community economic policy on regulation

In contrast, the Community does have a policy in relation to the broad direction of regulation, given that the primary function of its regulatory measures is to create a single internal market without trade barriers. Noting the deficit of the Community market and economy in relation to competitiveness, growth and innovation in comparison with the market of North America, the March 2000 European Council in Lisbon established broad policy lines for enhancing innovation and economic reform, building knowledge infrastructures, and modernising social welfare and education systems, and set the strategic goal for the next decade for the Union to become the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion.[908] Innovation was stated to be a key factor in enterprise policy and essential for European enterprises to be competitive.[909] To this end, five objectives were established, including that the Community's regulatory framework must be conducive to innovation, and not involve over-regulation.[910] The Commission stated that the administrative and regulatory environment is too complex and this continues to be a serious obstacle to the creation of new businesses and to entrepreneurship and also affects their capacity to innovate, as

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905 H W Micklitz, "Consumer Rights" in *Human Rights and the European Community: the Substantive Law, Volume III European Union - The Human Rights Challenge*, A Cassese, A Clapham and J Weiler (eds) and *Internationales Productsicherheitsrecht*, (Nomos, 1995).

906 *Eurobarometer: Public Opinion in the European Union*, European Commission, report No 47, 1 October 1998: the survey found that 88% of citizens approve of EU policy in consumer protection, although there was a variation from Denmark 66% to Greece 96%.

907 Ibid: 64% of respondents in the survey believed this, with three-quarters saying that consumer protection standards should be harmonised in the EU, presumably in ignorance of the extent of current harmonisation.

908 See Communication from the Commission to the Council and the European Parliament - Innovation in a knowledge-driven economy, COM (2000) 567.

909 Ibid.

910 Ibid.

"over regulation, for example in approval procedures for new products, raises development costs and increases time to market"[911].

In fulfilment of the Union's strategic goal "to become the most competitive and dynamic knowledge-driven economy in the world"[912] the Commission has said:

> "Enterprise Europe requires a revolution in our culture and attitudes towards entrepreneurship.
>
> Europe must re-examine its attitude to risk, reward and failure. Thus, *enterprise policy must encourage policy initiatives that rewards those who take risks.*" (original emphasis).[913]

Community policy is to simplify regulation[914] but there seems little evidence that this will have any impact in the field of product regulation. On the contrary, the trend has been and is continuing to be in the opposite direction.[915] There has been no intellectual attempt to consider the inter-relation of policies on consumer protection and regulatory simplification,[916] and it is not difficult to theorise that such policies could be mutually inconsistent. The undertaking of such a comparison would require data on costs and on levels of safety.

Some criteria on acceptable risks

Some legal judgments have been made on acceptability of particular risks but there is no attempt to approach this systematically or coherently. In clinical research on unlicensed medicinal products, where by definition the risk is less certain than for authorised products and the purpose is to produce data so as to clarify the actual risk, the criterion is that of minimal risk, which is defined[917] as either a small chance of a recognised reaction which is itself trivial (e.g. headache or lethargy) or a very

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911 Ibid. See also *White Paper on Growth, Competitiveness, Employment: the challenges and ways forward into the 21st century*, 1994; *Green Paper on Innovation*, COM (95) 688, 20.12.95; *Council Decision of 25 June 1996 on the implementation of a Community action programme to strengthen the competitiveness of European industry*, 96/413/EC, OJ No L167/55, 6.7.96.

912 Challenges for enterprise policy in the knowledge-driven economy, COM (2000) 256 final/2.

913 Ibid. The creation of a legal environment more conducive to risk-taking and job creation was also proposed in Opinion of the Economic and Social Committee on the 'Communication from the Commission – Challenges for the enterprise policy in the knowledge-driven economy' 2001/C 116/04, OJ No C 116/20, 20.4.2001.

914 A Business Environment Simplification Task Force (BEST), established in 1997, is charged with achieving this. The simplification programme for 2003 includes recasting the Cosmetics and Toys Directives and simplifying marketing authorisation variations for medicinal products: Communication from the Commission: Updating and simplifying the Community acquis, COM(2003) 71, 11.2.2003. It was said in *European Governance: A White Paper* Com (2001) 428, 25.7.2001 that Community legislation is too detailed and increasingly complex, and that this level of detail results in delay in adaptability.

915 The most significant measures are the extension of Directive 92/59 EEC on general product safety in 2001 and the introduction of comprehensive regulation of foodstuffs. New measures also regulate or extend prior measures on cosmetics, biocides and tobacco. Measures have been taken or are in hand to review and amend (and never remove controls from), amongst others, medicinal products, medical devices, machinery, low voltage, electromagnetic compatibility.

916 Note the approach in the UK Regulatory Reform Act 2001 that the burden of legislation should be proportionate to the benefit.

917 *Research involving patients* (Royal College of Physicians of London, 1990).

remote chance of a serious disability or death (e.g. comparable to flying in a scheduled aircraft). Greater than minimal risk is permissible in non-therapeutic research in certain circumstances.[918] Such research is, in the numbers of people that are by consensus included in tests, only capable of identifying "Type A" ADRs with an incidence of 1 in 250 patients, but incapable of detecting "Type B" ADRs.[919]

Court decisions in the regulatory context ultimately set society's legal standards of safety, even if retrospectively. A comprehensive analysis of national decisions is beyond the scope of this work, but the impression gained from a small sample of British decisions indicates the courts tend to adopt conservative approaches towards safety. Thus, it was held that labelling (warning of a risk of suffocation) is only relevant to cases where an inherent risk cannot be completely eliminated by modifying the construction and composition of the product (a toy) without altering its function or depriving it of its essential properties.[920]

In civil cases, courts are reluctant to set specific standards. Thus, the standard of disclosure that is set by civil law as required by a doctor advising a patient of the risks of proposed medical treatment in order to satisfy the necessary standard of care required under the civil law of negligence in English law has modified the patient's absolute right to know what risks are involved in undergoing or foregoing treatment, on the basis that:

> "... a decision what degree of disclosure of risks is best calculated to assist a particular patient to make a rational choice as to whether or not to undergo a particular treatment must primarily be a matter of clinical judgment. It would follow from this that the issue of whether non-disclosure in a particular case should be condemned as a breach of the doctor's duty of care is

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[918] Namely where (i) the risk is still small in comparison to risk of the disease, (ii) the disease is serious, (iii) there is great potential benefit in the importance of knowledge to be gained, (iv) there is no other means of obtaining the knowledge, or (v) the subject understands well what is involved and wishes to participate. Consent of the research subject, based on full disclosure of all available relevant information, is required as a basic principle. For further discussion of this subject and of rules where patients are legally or actually incapable of giving consent, see I Kennedy and A Grubb (eds), *Principles of Medical Law* (Oxford, 1998), ch 13.

[919] Type A reactions are related to the pharmacological effect of the drug, often in exaggerated form. They are dose-related, predictable once identified, and can occur in every patient. Type B reactions occur only in some people and are not part of the known pharmacology of the drug. They are not dose-related and are the result of unusual interaction of the patient with the drug. Type B reactions are described as bizarre but are usually more serious than Type A. These effects may be predictable where the mechanism is known (for example, the genetic polymorphism associated with some hepatic metabolising enzymes), or unpredictable (e.g. due to immunological processes). Type A reactions are by far the more frequent. See Rawlins, M D and Thompson, J W (1977). Pathogenesis of adverse drug reactions. In: Davies, D M (ed) *Textbook of Adverse Drug Reactions* pp 10-31 (Oxford/New York/Toronto: Oxford University Press). The incidence of some well-known Type B reactions is: aplastic anaemia with chloramphenicol, 1 in 6,000; jaundice with halothane, 1 in 10,000; deep vein thrombosis and myocardial infarction with oral contraceptives, both 1 in 10,000.

[920] *R v Felixstowe Magistrates ex p Top Toys Ltd* CO/67/93 (unreported), Buckley J, a decidion based on the interpretation of the 'general principles' for safety contained in Schedule 2 of the Toys (Safety) Regulations 1989. The judge opined that prohibitions of certain 'particular risks' referred to later in the Schedule (in this case risk of suffocation) had to be viewed as absolute in that a label or warning would not be sufficient to discharge the duty not to supply toys which carried that risk.

an issue to be decided primarily on the basis of expert medical evidence, applying the *Bolam*[921] test (which is the standard of the ordinary skilled man exercising and professing to have that special skill)".[922]

Courts have made individual decisions in a vacuum, without reference to an external matrix of criteria, and this can produce widely differing results. In the *Sidaway* case, Lord Bridge, in discussing the level of risk which should be disclosed, illustrated the standard to be expected in English law by referring to an incidence of risk as high as 1 in 10:

> "But even in a case where, as here, no expert witness in the relevant medical field condemns the non-disclosure as being in conflict with accepted and responsible medical practice, I am of the opinion that the Judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it. The kind of case I have in mind would be an operation involving a substantial risk of grave adverse consequences, as, for example, the ten per cent risk of a stroke from the operation which was the subject of the Canadian case of *Reibl v. Hughes* (1980) 114 DLR (3d) 1. In such a case, in the absence of some cogent clinical reason why the patient should not be informed, a doctor, recognising and respecting his patient's right of decision, could hardly fail to appreciate the necessity for an appropriate warning."[923]

As a decision of the House of Lords, the *Sidaway* case remains an authoritative statement of English law. However, the equation of a "substantial risk of grave adverse consequences" with a ten per cent risk of stroke in 1985 has been much questioned.[924] Judgments in the case also canvassed the possibility of 3½% or 4% risks. In any event, the magnitude of the difference between risks of the order of 1% to 10% in the law of the standard of disclosure for medical treatment as compared with risks with an incidence of 1 in 10,000 in the context of the evaluation of safety for medicines regulation is startling. In an Australian medical negligence case a doctor was found negligent for not disclosing a 1 in 14,000 risk of blindness from an eye operation on the basis that he should have appreciated the patient's desire to know of that risk.[925]

In contrast,[926] the predominant approach in jurisdictions of the United States is for the learned intermediary physician to be required to disclose *all* known risks of whatever magnitude. In its most extreme form, although this was only adopted in a minority of American States, the view is taken that an objective criterion of what is a sufficient disclosure of risk is necessary to ensure that the patient is

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921 *Bolam v. Friern Hospital Management Committee* [1957] 2 All E.R. 118.

922 *Sidaway v. Bethlem Royal Hospital Governors* [1985] A.C. 871.

923 *Sidaway*, supra p891.

924 See *Medical Law: Text with Materials* Kennedy I.G. and Grubb A. Butterworths. 1994. 2 ed.

925 *Rogers v Whitaker* (1993) 4 Med. L.R. Note that this case criticised the approach of *Sidaway*.

926 For an analysis of the differences between the English and American approach, see I Kennedy and A Grubb (eds), *Principles of Medical Law* (Oxford, 1998), para3.104 et seq.

enabled to make an intelligent decision and cannot be left to be determined by another person, such as the advising or treating doctor:

> "Respect for the patient's right of self-determination on particular therapies demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves".[927]

Cost-benefit assessment

It has been said that individual decisions on the safety of products should be based on risk-benefit assessments. The efficiency and comparative effectiveness of regulatory measures, whether as systems or individual enforcement measures, can only ultimately be measured through cost-benefit assessments.[928] The Community has not undertaken this save in relation to the introduction of new measures,[929] but otherwise does not have the methodology to review existing mechanisms.[930] These are serious failings and mechanisms should be introduced that would enable Safety Impact Assessments to be carried out on regulatory mechanisms.

An assessment of the safety effectiveness and comparative efficiency of measures are, of course, entirely consistent with consumer policy. The UK National Consumer Council has promulgated a Consumer Impact Assessment as a good practice tool to assess whether markets and public services are working in the consumer interest, which requires answers to the following questions:

1. What does the policy or regulation aim to achieve?
2. What are the options for achieving the objectives?
3. What are the impacts – the costs and benefits to consumers – of each option?
4. Are the consumer impacts significant? How large are they in relation to other impacts?
5. What consumer safeguards can be built in to each of the options without causing significant harm to other interests?

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927 *Canterbury v. Spence* 464 F 2d 772 (DC, 1972), although the decision in that case was that reasonable disclosure is required.

928 C R Sunstein, *Risk and Reason* (Cambridge, 2002).

929 It is proposed to introduce a new, comprehensive Impact Assessment for Community measures that would include safety and health issues, at proportionate depth: Communication from the Commission on Impact Assessment, COM(2002) 276, 5.6.2002. J Froud, R Boden, A Ogus and P Stubbs, *Controlling the Regulators* (Macmillan Press Ltd, 1998) found that an impact assessment process is difficult to operate effectively, certainly in affecting regulatory outcomes, but its existence as a formalised regulatory procedure has restrained the extension of bureaucratic regulatory power.

930 A relevant issue is that various studies have estimated that the burden of Community regulation costs 2-5% of GDP: Mandelkern Group on Better Regulation: Final Report, 13 November 2001.

6. How far can the costs and benefits to consumers be quantified without disproportionate effort?

7. What are the uncertainties and assumptions in the calculations?

8. How do the costs and benefits compare for each option?

9. What is the preferred option, and what consumer safeguards should be included?

10. How will the consumer impacts of the policy be monitored and evaluated?

There are few reliable data on the socio-economic costs of injury.[931] It would be necessary to include figures for medical costs, social security, other insurance, dependents, lost production, and pain and suffering, all of which have different values and computational methods in Member States.[932] ECOSA believed that the best estimates available in 2001 were:[933]

Accident location	Economic Burden (Euro)
Home and leisure	230,000,000,000
Road	166,000,000,000
Workplace	20,000,000

Although these figures are not reliable, they indicate that the cost of home and leisure accidents is the most significant area for policy, and it therefore follows from the other evidence of this work that focussing on product safety and human behaviour are important. Some work is available on the difficult issue of valuing a life,[934] such as the US figures at Table 12, which indicate also some of the preventive actions that can be taken.

No calculations can be undertaken on cost-benefit issues on product safety regulation given the absence of reliable data and agreed methodology. ECOSA merely points to a general indication that the level of EU funding for prevention and regulation of home and leisure accidents lags far behind

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931 It seems that only one recent significant study has been undertaken, on medical costs in the Netherlands: *Costs of injuries in the Netherlands* (Consumer Safety Institute and Erasmus University, 2000). The results are summarised in *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001). Earlier work includes M W Jones-Lee, *The Economics of Safety and Physical Risk* (Basil Blackwell, 1989).

932 For variations in approaches to computation and valuation of legal compensation awards alone, see D McIntosh and M Holmes, *Personal Injury Awards in EC Countries* (Lloyd's of London Press, 3ed, 2003).

933 *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001): it admitted that various methodologies were employed that were not fully comparable.

934 See D J Ball et al, *The Optimisation of Consumer Safety* (Middlesex University, 1998).

those for workplace and road traffic accidents, whereas this is in inverse proportion to their calculations on the magnitude of the economic burden of these three categories: Figure 1.[935]

Conclusions

The conclusions that can be drawn from the above analysis are as follows. First, the legislation is inconsistent in its use of different tests for safety in different sectors. Secondly, although the achievement of "safety" or "a high level of protection of health and safety" in the manufacture and use of products are laudable aims of socio-legal policy, they are incoherent as legal tests since they are subjective and necessarily involve quantification in order to apply them in a meaningful manner. Thirdly, a logical approach would be to adopt a risk-benefit test for the marketing of products, which would be coupled with formal and consistent risk-acceptability criteria, and a requirement for manufacturers to perform and constantly update formal, documented risk assessments on their products so as to demonstrate conformity with the required level of safety. Such an approach would be consistent with the agreement of a coherent Community social policy that defines the acceptability of individual risks is required. This follows from recognition of the fact that responsibility for safety must ultimately be shared between all involved:

> "With respect to safety, no one can opt out of making a positive contribution, whether the Commission, Member States nationally and locally, manufacturing industry, retailing and distribution, trade unions, consumer organisations and indeed individuals in their capacity as consumers, and particularly as parents in charge of small children."[936]

The above approach is based on logic and empiricism. However, the regulatory system continues to function without either comprehensive statistics or the mechanisms to collect them and to set a coherent integrated policy on what levels of safety should be acceptable for particular products. The realisation that safety is not an absolute norm may not be recognised by consumers (or certainly popular media writing) but the concepts of risk management systems and the need to manage variable risks are now widespread in industry and regulatory circles. There is, therefore, a disconnect between professional and consumer understanding over product safety, risk, acceptability and where responsibility lies.

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935 *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001). It attributes the difference to differences in the public and political perception of risk between the three categories: "Small incremental increases in the death toll are not noticed regardless sometimes of the overall total. Put bluntly one child killed is not often [but] news five or six in the same event is. However this is very unlikely to happen as a result of a home or leisure accident and more likely to be a transport accident."

936 Opinion on the proposal for a Council Directive concerning general product safety, OJ No.C 75/1, 26.3.90.

In this context, as illustrated in the case histories, public confidence becomes an important issue in situations of crisis or perceived crisis, where objective scientific analysis becomes of lesser importance and may indeed be mistrusted, and where political solutions are required, which may override logical solutions. In more normal circumstances, the more rational approach of scientific evaluation can play a greater role.

20. CONCLUSIONS

This analysis has traversed an extremely wide canvas of complex legal provisions, encompassing several adjacent but discrete product areas, most of which are different in their internal structure, and are substantial in both scope and in detail. Regulators, economic operators and lawyers tend in practice to operate solely within a discrete system, and few attempt to acquire an overview of the various systems. This thesis has tried to do just this. What has been seen? Is there a coherent system? What mechanisms are employed to deliver product safety? Do the mechanisms in fact achieve their objectives? Are they efficient or redundant? How would one know whether regulation delivers safety or whether the current systems are efficient?

The policy objective: trade or safety?

Chapter 3 identified that the constitutional basis of the Community legislation that regulates product safety is founded on trade considerations, and safety is merely a subsidiary consideration. There may be a permanent conflict in reconciling the demand of free trade and valued social goals of safety and consumer protection.[937] If so, Community policy clearly places trade issues above the social goals, although the ECJ has said, albeit so far in a small number of cases, "in principle the requirements of the protection of public health must unquestionably be given precedence over economic considerations".[938] It may be that this setting of priorities is based on a judgment that safety issues should be of secondary importance to trade issues,[939] and that the prevailing level of safety in the Community is satisfactory, but the former would not appear to command overwhelming support given the many policy statements on the importance of safety,[940] plus the fact that prior national legislation was directed solely at safety,[941] and the latter has not been measured, demonstrated or asserted by the Community institutions.

Further, it does not necessarily follow that regulation inspired by trade rules that places the achievement of safety as the central requirement in practice should relegate that safety requirement

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937 K Armstrong and S Butler, *The governance of the Single European Market* (Manchester, 1998), p 145.

938 Order of the Court of Justice in Case C-180/96 R *United Kingdom v Commission* [1996] ECR I-3903], paragraph 93; judgment in Case C-183/95 *Affish v Rijksdienst Keuring Vee en Vlees* [1997] ECR I-4315, paragraph 43; order of the Court of First Instance in Case T-136/95 *Industria del Frio Auxiliar Conservera v Commission* [1998] ECR II-3301, paragraph 58; and order of the President of the Court of First Instance I Case T-70/99 R *Alpharma v Commission*[1999] ECR II-2027, paragraph 152).

939 It is tantalising to speculate that one reason why data on product safety is not collected systematically is that it might indicate an absence of distortion in trade within the internal market and hence undermine the constitutionality of the existing legislation.

940 The Agencies and competent authorities that enforce the safety provisions and the competition aspects are already separate.

941 In the United Kingdom, see the Consumer Safety Acts 1961 and 1978, and the Consumer Protection Act 1987, Part II.

to subsidiary importance with limited constitutional relevance.[942] If this is correct, there is a strong argument for amending the Treaty so as to enable measures to be based upon the express policy criterion of achieving safety, and achieving a high level of protection.

There would be several consequences of taking safety seriously in this way. First, a fresh view could be taken of the institutions and mechanisms that are necessary to achieve product safety, rather than continuing with those that have emerged as a result of historical fortuitousness within the evolution of trade policy. Secondly, systems could be instituted for the measurement of what level of safety exists over time and whether it is increasing or diminishing. This would assist in the comparative and political conclusion of whether the goals of achieving "safety" and a high level of protection are achieved, and whether action needs to be taken. It would also enable an informed answer to be given to the question, that is currently a matter entirely of speculation and prejudice, of whether resources are being used efficiently, and thus whether there in fact exists unnecessarily expensive over-regulation or insufficient control. The conclusions may well differ between the different product sectors or mechanisms. A review of efficiency might, for example, point to the conclusion that changes are needed in the current functions and operation of the various actors and organisations involved.

Overview of mechanisms

Part One demonstrated that discrete regulatory systems have emerged in Community law for various product sectors since the 1960s and crystallised particularly during the 1990s. Each regulatory regime has its own approach to achieving safety, and its own particular series of regulatory requirements, which can be complex. Interventionist regulatory mechanisms have, therefore, replaced the previous non-interventionist market-based product liability mechanism, both in theory and practice, as the pre-eminent mechanism for delivering product safety. The regimes have come about either as emotional-political responses to serious incidents that have captured the public attention,[943] and/or as side effects of the macro-economic and political aims of developing the European trading bloc.[944] The regulation of specific sectors has occurred at different times during

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942 The question arises whether it would it be constitutionally sound for safety to replace trade as the primary consideration, or for both goals to be given equal prominence: that is beyond the scope of this work.

943 Notably thalidomide in the 1960s and BSE/CJD in the 1990s. See also the US Transportation Recall Enhancement, Accountability and Documentation Act 2000 passed in response to the extensive recall of Firestone tyres.

944 For example, initial proposals for harmonised legislation, and individual developments such as the 1993 move to create a centralised European medicines agency and the 2001 extension of post-marketing obligations on Member States, manufacturers and distributors for consumer products.

the past 40 years along independent lines albeit with some similarities, resulting in what has been called a heterogenous network of regulatory patterns that can only be understood historically.[945] These observations account for a number of facts, not least of which is that the individual systems are not integrated, that they adopt different mechanisms and legal tests, and that there are significant gaps in the mechanisms that exist in the different systems.

A further general finding is that the approach adopted in Community legislation is to state norms, or requirements based on generalised outcomes. These need to be, and often are, supplemented by more detailed subsidiary requirements, whether contained in standards or in (often extensive) guidance. Such a system provides for flexibility in application in individual situations and flexible evolution and prompt amendment, but the extent and complexity of the material requirements can be daunting and confusing. It is certainly important to ensure that standards and guidelines are produced speedily and that their content is adequate. The trend towards adoption of international standards is encouraging. However, the statement of generalised legal requirements leads to uncertainty: can consumers, industry and regulators know whether the essential requirements of the Machinery Directive are satisfied by an individual machine?

Part Two examined the general mechanisms that are used in the various regimes. It attempted to define the various components of pre- and post-marketing requirements that might be expected to comprise such mechanisms (set out in theoretical frameworks), but found that the extent to which such requirements in fact exist within the various product regimes differs considerably. Even where a specific obligation can be found in a particular sectoral regime, its extent and wording often differs from what might be expected, and the result is an inconsistency of approach across the different sectors. Nevertheless, an impressive range of regulatory techniques is deployed across the regimes, and all of them could be expected to contribute to safety.

In general, the vertical Directives lay down pre-marketing requirements but not post-marketing requirements (the primary exception being medicinal products) and, in contrast, the emphasis of the horizontal GPSD for consumer products is on post-marketing requirements.[946] The latter requirements on producers and distributors are stated in broad terms. In contrast, pre-marketing requirements for some vertical Directives are often very detailed (medicines, machinery, medical devices, telecommunications equipment) and such requirements thereby "define" safety. Thus,

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945 C Joerges, "Paradoxes of Deregulatory Strategies at Community level: The example of Product Safety Policy", in G Majone (ed), *Deregulation or Re-regulation? Regulatory Reform in Europe and the United States* (Pinter Publishers, 1990).

946 Directive 2001/95/EC.

safety for these products is defined in the pre-marketing context and in terms of the specific and detailed considerations that are included in the legislation. In the post-marketing situation, the GPSD requirements apply to consumer products only and it is curious that post-marketing requirements are not generally otherwise contained in vertical Directives for non-consumer products. Employers do have responsibility for supplying workplace products that comply with the New Approach essential requirements or their equivalent, and should have contractual recourse to suppliers, and for maintaining them in such condition,[947] but there is no reason why producers and suppliers should not be subject to post-marketing duties equivalent to the GPSD.

The different product regimes differ over who has primary responsibility for safety. At one extreme, primary responsibility for marketing medicines and biocides rests with the authorities, in both the pre- and post-marketing situations, and manufacturers have subsidiary requirements in relation to production of safety data. At the other extreme, responsibility for marketing general consumer products rests with manufacturers, and authorities have no involvement within the regulatory process of individual products other than in relation to general market surveillance and enforcement. The regimes for cosmetics and New Approach products contain hybrid aspects of both extremes, such as through official approval of listed substances or through notified bodies.

It was seen that the essence of New Approach pre-marketing safety mechanisms is the application of a *process* in which a manufacturer undertakes a documented, structured evaluation of whether his product satisfies essential safety requirements (stated in the form of broad principles, so as to have wide application without limiting the manufacturer as to how each will be satisfied). The reliance on such a structured approach has the advantages of subsequent audit verification and of directing the manufacturer's mind to whether the product is safe in all respects. The essential requirements must be kept up-to-date and mechanisms exist to adapt them to scientific and technical progress. Undertaking a formal risk assessment is implicit in this process but is not always a legal requirement. The same transparent approach should in theory apply to all other products, whether authorised by manufacturers or authorities, but the degree of transparency is not the same under all product regimes.

The achievement of safety depends to a significant extent on the application of accumulated knowledge and of common sense. It has been recognised that the impact of these regulatory systems has imposed appreciable cost on industry, and this may have both contributed to product

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947 Directive 89/655/EEC as amended by 95/63/EC.

safety by prohibiting smaller manufacturers from the market, and adversely affected safety by encouraging the cutting of corners. Empirical evidence is lacking here, so no view can be taken on what effects have in fact occurred.

In broad mechanistic terms the focus of the approach to safety in virtually every sectoral system is on *preventative* mechanisms.[948] Prevention of hazard is at the core of pre-marketing controls, and in the post-marketing context the aim is to minimise the risk of injury in relation to products already marketed or yet to be marketed. Prevention is, therefore, a logical place to start in erecting regulatory systems. There is, however, an increasing realisation that reliance solely on pre-marketing prevention techniques is unlikely to provide sufficient protection and that post-marketing techniques need to be introduced, without which there will be a regulatory gap.[949] This has long been recognised in relation to medicinal products, and has now been introduced for general consumer products with the 2001 extensions to the GPSD. The Commission's insistence that GPSD post-marketing mechanisms do not apply to New Approach products because "New Approach directives regulate all aspects of safety and categories of risk relating to the products to which they apply"[950] is absurd and incorrect in law.[951] The development of an efficient and effective integrated post-marketing vigilance system seems to be a priority. If this is not done, the imposition of such a large regulatory system may simply have replaced market failure with regulatory failure.[952]

A number of problems with the current state of post-marketing mechanisms were identified. Post-marketing safety involves effective and speedy collaboration between a number of actors. Only the GPSD sets out, in the form of general principles, a coherent set of post-marketing requirements for producers, distributors (who have otherwise been largely untouched by legal obligations) and regulators, and there is no reason in principle why these should not apply for all other product sectors. In the medicines, and recently medical devices, sectors integrated and effective vigilance systems exist, which are elaborated largely in guidelines. The use of guidelines has enabled flexible evolution of workable systems, but the patchy underpinning by legal obligations leaves lacunae.

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948 Consolidating a culture of risk prevention is similarly a strategic aim in workplace safety policy: Communication from the Commission: Adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006, COM(2002) 118, 11.3.2002.

949 C Joerges, "Paradoxes of Deregulatory Strategies at Community level: The example of Product Safety Policy", in G Majone (ed), *Deregulation or Re-regulation? Regulatory Reform in Europe and the United States* (Pinter Publishers, 1990).

950 Communication form the Commission to the Council and the European Parliament: Enhancing the Implementation of the New Approach Directives, COM(2003) 240, 7.5.2003, para 2.5.5.

951 It is contrary to Directive 2001/95/EC, article 1.2.

952 G Majone, The Rise of the Regulatory State in Europe" *West European Politics* (1994) 17:3, 77-101, 82.

Theoretical analysis identifies the importance of a coherent, integrated system for market surveillance and enforcement, and serious shortcomings are found with the current state of the Community systems. Recent reviews of the GPSD and New Approach mechanisms, as well as some individual New Approach Directives and the pharmacovigilance system,[953] have consistently identified problems arising out of a lack of coordination of safety data,[954] communications between national regulators, efficiency in expert assessments of product safety, delay and inconsistency in taking decisions, and policies on enforcement. There is a potentially bewildering maze of unharmonized and possibly conflicting responsibilities between producers, distributors and regulators, national offences, enforcement powers, authorities, policies, resources, and decisions. Notwithstanding political reluctance arising out of the subsidiary principle, from the perspective of achieving safety[955] the current fragmented approach should be replaced by a consistent, unified approach, and hence the case for a single European Product Safety Agency is strong.[956]

Legal tests for safety

The essential issue is whether products are safe to use. Tests exist in most product sectors for the level of safety which products must meet in order to be legally placed on the market. The primary conclusions of this study are that Community legislation is inconsistent and incoherent in the tests and definitions that are given for product safety, and there is in any event no consensus over what level of safety should be achieved. The legal tests differ considerably as between different sectors and also, even within sectors, in relation to the tests for placing products on the market and for removing them when they are unsafe. This situation would logically lead to differences in the safety of different product sectors and even similar products within the same sectors. The current system rests on a concept of safety that is subjective and undefined, and hence involves very considerable elements of uncertainty for regulators, economic operators, consumers and courts. The terms "safety" and "a high level of protection" are legally incoherent in that they are imprecise and

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953 Communication from the Commission: *A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient- A Call for Action* COM(2003) 383, 1.7.2003, section 2.1.

954 See Recommendation of the Council Concerning the Establishment of Data Collection Systems Related to Injuries Involving Consumer Products, OECD, C(77)139.

955 Although the Commission is reluctant to delegate its powers, budgetary considerations are pressuring change: Communication from the Commission: Externalisation of the management of Community programmes including presentation of a framework regulation for a new type of executive agency, COM(2000) 788, 13.12.2000; Communication from the Commission: The operating framework for the European Regulatory Agencies, COM(2002) 718, 11.12.2002.

956 This view is shared by G Howells, *Consumer Product Safety* (Dartmouth, 1996), p 47. The Commission has itself recently justified a proposal to establish a European Centre for Disease Prevention and Control on the basis of the need for co-ordination of authoritative, independent scientific advice on serious health threats, enabling a rapid, consistent, EU-wide response: see Explanatory Memorandum COM(2003) 441, 23.7.2003.

unmeasurable and could be used in such a way that the existence of any hazard, however insignificant in absolute or comparative terms, could justify regulatory intervention.[957]

It makes rather more sense to adopt tests based on risk-benefit criteria[958] but in order to apply such tests it is necessary both to define and quantify individual risks and benefits with particular products. On this basis, all product regulation should require a formal risk assessment to be carried out. Risk assessment requires a judgment as to the acceptability of the defined and quantified risks and benefits, and in order to provide a framework for acceptability in the prevailing social context, it is necessary to define a Community product safety policy.[959]

However, in the absence of absolute norms on safety, subjective criteria of acceptability are applied in practice. This is only recognised explicitly in the GPSD and (stated in reverse) for biocides, but is implicit for medicines. Tests in other product sectors seem to require a complete absence of hazardous effects, at least when used "as intended", but this is unreal. The legal tests need reviewing and there is a strong argument for adopting a consistent approach.

Supranational governance and multiple actors

Chapter 18 found that regulation of product safety in the Community involves the complex inter-action of a number of different actors within novel systems of supranational governance that are fairly new and continuously evolving. A deficit in democratic accountability can be said to exist, which is compounded by the absence of consensus over what may be considered to be acceptable levels of risk. Consumer bodies are concerned by their inability to influence what are seen as increasingly remote processes, and political oversight is currently exercised through committees of Member State representatives and, to a fairly limited extent, the European Parliament. There is a case for a clearer mechanism of political oversight which would deliver consensus on criteria for safety-acceptability and oversee its achievement in practice. However, a significant level of public accountability emerges from media scrutiny of individual issues, although this is not always informed and is rarely capable of subtlety.

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957 See W K Viscusi, op cit, for a similar criticism of the United States approach.

958 As is in practice the case for medicines, albeit not sanctioned in the legislation.

959 C Joerges, supra, called in 1990 for a consistent European "safety philosophy" and argued in 1988 that market integration – to say nothing of social protection – requires a positive European product safety policy and new instruments of action, but there has been little progress towards coherence.

Measuring intervention: the empirical approach

Has a case been made for the creation of such a large body of regulation, bringing with it significant costs?[960] How would one know whether either safety or a high level of protection has been achieved? How would one know if the actual level is unacceptable or has improved or deteriorated? Are the individual mechanisms analysed in Part Two effective in ensuring safety, and to what extent are they efficient? Are other mechanisms more effective or efficient? Should some existing mechanisms be removed or altered, or other mechanisms be introduced?[961]

It has been suggested that the only reliable way to answer these important questions is with empirical data. One would logically expect to be able to provide answers to the following empirical measurements:

- the level of safety that applies (more specifically the level of risks and benefits that apply) in a specific product sector, or for a specific product, is "x";
- this level is unacceptable, both by comparison with another sector's level and on the basis that it does not achieve the policy target level that should apply;
- the proposed mechanism is appropriate and will increase the safety level to that desired;
- the proposed mechanism has favourable cost-benefit balance; it can then be shown retrospectively that the incremental increase in safety exceeds the incremental increase in cost.

Data on the number of products in circulation is not available. Data on the number, seriousness and incidence of safety incidents is rarely collected or published, and the Community has virtually no mechanisms to collect relevant data. There are, admittedly, enormous difficulties in evaluating and comparing data, and in agreeing on levels of acceptability as between different types of injuries and different product sectors, but the absence of such data and policy decisions based on it clearly constitutes a serious systemic failure of the Community's social and industrial policy in ensuring the delivery of efficient and tangible safety.

The Community does attempt to carry out cost impact assessments of legislation before it is promulgated but recognises that there are serious shortcomings with these processes and with the

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960 Viscusi castigated a similar lack of justification for the introduction in 1972 and continuation of the United States Consumer Product Safety Commission: W K Viscusi, *Regulating Consumer Product Safety*, op cit.

961 As Breyer points out, we regulate only some, not all, risks that fill the world: S Breyer, *Breaking the Vicious Circle* (Harvard, 1993). Nevertheless, risk to life and/or health is one of the situations where consumers do not accept pure self-regulation: Soft law in the European Union: A discussion paper (National Consumer Council, 2001). It should be remembered that, as now, different product types present greater or less risk, and it may be proportionate to regulate them with differing approaches.

production of reliable results. This means that there are serious problems over undertaking subsequent evaluations of the impact of legislation, whether it is effective or efficient, and what change any subsequent amendments may have. Evaluation is largely impressionistic.[962]

The production of data would have other benefits. Baldwin has shown that one of the most important reasons for under-performance by rule-makers is where there exists a top-down approach that assumes there will be no enforcement problems and in which inspectors are not involved in policy-making. He identifies the need for a system of collecting and reviewing data and appropriate amendment of the rule.[963] Similarly, Joerges has said:

> "A product safety policy needs, if it is to justify its procedures, data on accident figures and information on circumstances surrounding accidents, to derive priorities and develop appropriate strategies to avoid hazards."[964]

The greater availability of data would not be without difficulty in making comparisons and in trying to reconcile inconsistencies. But it would enable greater rationality to inform debate and decisions on product safety, enable improved cost-benefit calculations to be made, and make decisions less political and hence uncertain and subject to ideological influences. The introduction of any increase in regulation aimed at improving the safety of product use should be accompanied by appropriate mechanisms (a) accurately to predict and later to verify the marginal increase in safety, (b) measure this against the marginal increase in costs and any increase or deterioration in other benefits, and (c) conclude whether the resulting balance is acceptable and desirable.

A major finding of this thesis is, therefore, that it is unmeasured whether the considerable complexities of European product safety regulation succeed in delivering safety, or whether the various systems and mechanisms are effective, redundant or efficient. There are also no mechanisms which would systematically produce data on which such a conclusion could be reached. It is suggested that such systems are needed, since it is worth trying to verify the answers to the questions posed in view of the importance to society of achieving safety and of having regulatory systems and laws that work and work efficiently.

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962 For example, G Howells, *Consumer Product Safety* (Dartmouth, 1998) p8 states: "A balance needs to be struck. Although one does not want to impose unnecessary costs, third party certification is in fact a very practical way of promoting product safety. There seems to be too great an emphasis on manufacturer's self-declaration." We currently have no way of knowing whether or not that view is correct, and the same applies to suggestions above, such as the need for vigilance systems for New Approach and other sectors.

963 R Baldwin, *Rules and Government* (Oxford, 1996), p 166.

964 C Joerges, "Paradoxes of Deregulatory Strategies at Community level: The example of Product Safety Policy", in G Majone (ed), *Deregulation or Re-regulation? Regulatory Reform in Europe and the United States* (Pinter Publishers, 1990).

A system based on incommensurability

Nevertheless, it is undeniable that the product regulatory systems have been constructed in the expectation that they will both deliver an acceptable level of product safety and reassure the public to that effect. Reassurance and public confidence are important aspects of the system. A cost-benefit judgment is, therefore, made by legislators and society that the system has value, even if such an assessment is impressionistic. The regime would not otherwise ultimately be tolerated: either consumers would demand extensions in the system as each new adverse event occurs, or industry would refuse to comply with what it would see as a prohibitively costly system.

The response to the argument for empiricism made above is based on the finding that a system can accommodate differing views on value judgments if it provides sufficient transparency, accountability to stakeholders, and opportunity for robust debate, leading to broad consensus. Such a system should be robust enough to permit different actors to exercise differing judgments or discretions on issues on which there can exist a multiplicity of opinions. There can be broad agreement on the issues of principle ("safety" or "a high level of protection") but differing valid views on specific examples. The product regulatory regimes analysed here present mixed results on these tests. Vigorous public debate occurs after media coverage of what are perceived to be major crises, but this often takes the form of searching for someone to blame rather than examining competing values and debating issues of fine judgment. Public debate on the level of safety to be expected from different products (eg how many injuries and of what severity are acceptable for specific products) rarely occurs.

Transparency is not assisted by the incoherence of the legal tests for marketing products which has been found in virtually all sectors, despite the publication of extensive testing or essential requirements. There is a reasonable amount of transparency over individual decisions on product approval for medicines (authorities publish reports evaluating their risk-benefit assessments on products), and although at least some manufacturers of New Approach products should carry out risk assessments on individual products, more could be done in this respect. There is little transparency over post-marketing decisions on product safety, but this should be improved by introduction of the notification and publication provisions of the GPSD, under which producers and distributors must notify the authorities of dangerous products and the authorities will then publish information on the existence of the problem.

The criterion of accountability to stakeholders similarly results in a mixed response. Making individual actors accountable presents problems in a complex multiple-actor system. One finding was that accountability of regulators would be improved at Community level by oversight by the European Parliament, as on the American model. Accountability of commercial enterprises depends on the existence of effective competent authorities using techniques such as inspections and sensitive market surveillance and enforcement. Here, the picture is mixed: there is evidence of effective activities by authorities in the medicines and medical device sectors, but the reports on the GPSD and some other sectors reveal concerns about the resources and effectiveness of national authorities. A major issue is the lack of coordination in many sectors (medicines and possibly medical devices excepted), and hence the potential for inconsistency, amongst the large number of national regulators.

A further problem is the reluctance of the courts to assume jurisdiction to review decisions made by regulators, on the basis that safety decisions involve complex technical matters that are not appropriate for courts. If judicial review mechanisms are limited to procedural transgressions or to *Wednesbury* unreasonableness grounds, there remains an accountability deficit to stakeholders. This should be remedied by providing appeal mechanisms to appropriate committees, on which there might be suitable expert and consumer representation.

A vision of a future system

In conclusion, there is a strong case for a single European Product Safety Agency, comprising divisions that deal with medicines, medical devices, machinery, electricals and electronics, motor vehicles, and general consumer products[965]. Staff would have considerable independence, but be rotated amongst different sectoral divisions, in order to give consistency of approach and protect against regulatory capture. The statistical power of such an Agency in relation to post-marketing vigilance would be considerable, and should be able to identify safety issues quickly and efficiently. Decisions could be made quickly, based on best available expert advice and information, and be consistent (horizontally across sectors and over time) and efficiently made, based on unified lines of communication. Enforcement issues would be delegated to national authorities but coordinated for consistency. Such an Agency, rather than the Commission as at present, would have authority to

[965] The 2001 GPSD amendments are modelled on the operation of the US Federal agency, the Consumer Product Safety Commission, but Member States' reluctance currently prevents adoption of such a centralised agency in Europe. This raises issues of how well the legislation will work. The USA has other Federal agencies: Food and Drug Administration; National Highway and Transportation Safety Administration; Bureau of Alcohol, Tobacco and Firearms. Fusing these into a single agency might create an entity which is too large and unwieldy, but may achieve closer collaboration and consistency.

take executive decisions and be accountable to the European Parliament. There would be an appeal mechanism on individual technical decisions (in addition to judicial review on procedural grounds) to an independent committee comprising regulators, consumers, industry, and regulators.

The Agency would be responsible for proposing, for agreement by Parliament, Council and Commission, Community policy on safety issues, including statistical criteria on the acceptable levels of the incidence and severity of adverse events with particular products. Enforcement policy would also be published. It would also be charged with stimulating debate on safety issues and on what levels of incidence and severity of differing adverse events are acceptable across all product sectors. Data would be systematically collected and published, thereby facilitating review of the effectiveness and efficiency of legislative techniques and enforcement policy. As a first step, the legal tests for placing and removing products on the market would be unified and rationalised, based on a risk/benefit assessment and satisfaction of acceptability criteria. This would require formal risk assessments to be undertaken, but would also recognise that some level of injury associated with product use is in fact socially and legally acceptable.

Ultimately, many of the imperfections which have been found in the legislation and its mechanisms stem from the fact that its constitutional base is freedom of movement of goods. The entire purpose and operation of the legislation would come into effective focus if the legislation could be based squarely on real social purpose, which is to maintain the safety of the European populace. Given that the regulatory mansion has now been built, is it not time to see it as it is?

TABLE 1: Selected summary of legal tests for safety

	Placing on the market	**Removal from the market**
Medicinal products		
- centralised approvals	Authorisation shall be refused if, after verification of the information and particulars submitted, it appears that the quality, the safety or the efficacy of the product have not been adequately or sufficiently demonstrated by the applicant, or that the particulars and documents are incorrect.[966]	A Member State may suspend an authorisation where urgent action is essential to protect human health.[967]
- mutual recognition approvals	Authorisation shall be refused if, after verification of the particulars and documents, it proves that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant.[968]	The competent authorities shall suspend or revoke an authorisation where the product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared.[969]

966 Regulation (EEC) No 2309/93, Article 11.
967 Regulation EEC No 2309/93, Article 18.4.
968 Directive 2001/83/EC, Article 26.
969 Directive 2001/83/EC, Article 116.

New Approach - machinery - medical devices	If it does not endanger the health or safety of persons when properly installed and maintained and used for its intended purpose.[970] It must satisfy the essential health and safety requirements.[971] If it complies with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with its intended purpose.[973] It must meet the essential requirements in Annex I.[974]	A Member State shall take all appropriate measures to withdraw, prohibit or restrict machinery where it is liable to endanger the safety of persons when used in accordance with its intended purpose.[972] A Member State shall take all appropriate interim measures to withdraw, prohibit or restrict a device where it ascertains that it may compromise the health and/or safety of patients, users or, where applicable, other persons, when correctly installed, maintained and used for its intended purpose.[975]
Cosmetics	A product must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of its presentation, labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer .... Member States must ensure that cosmetic products conform to the Directive and its	A Member State may provisionally prohibit a product which it notes, on the basis of a substantiated justification, represents a hazard to health.[977]

970 Directive 98/37/EC, Article 2.1.
971 Directive 98/37/EC, Article 3.
972 Directive 98/37/EC, Article 7.1.
973 Directive 93/42/EEC, Article 2 as amended by 98/79/EC, Article 21.2(b): note that the previous unamended wording was similar to that of the machinery Directive.
974 Directive 93/42/EEC, Article 3.
975 Directive 93/42/EEC, Article 8.
976 Directive 76/768/EEC, Article 2.

	Annexes.[976]	
Biocides	A product must be authorised in accordance with the Directive.[978] An authorisation may only be issued if (a) the active substances are in an approved list, (b) it is established in the light of current scientific and technical knowledge, and is shown from appraisal of the dossier, that the product, inter alia, has no unacceptable effects on the target organisms, or itself, or as a result of its residues, on human or animal health, directly or indirectly or on surface water and ground water, or on the environment, (c) the nature and quality of its active substances and impurities can be determined, (d) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the product.[979]	An authorisation shall be cancelled if the conditions of Article 5.1 are no longer satisfied.[980] A Member State shall modify the conditions of use of an authorisation and, in particular, the manner of use or the amounts used, where it considers it necessary on the basis of developments in scientific and technical knowledge and to protect health and the environment.[981]

977 Directive 76/768/EEC, Article 12.1.
978 Directive 98/8/EC, Article 3.1.
979 Directive 98/8/EC, Article 5.1.
980 Directive 98/8/EC, Article 7.1.
981 Directive 98/8/EC, Article 7.4.

Tobacco	The yield of cigarettes shall not be greater than: - 10mg per cigarette for tar, - 1 mg per cigarette for nicotine, - 10 mg per cigarette for carbon monoxide.[982]	No provision
Consumer products[983]	The product must be safe.[984] A safe product is one which, under normal or reasonably foreseeable conditions of use including duration does not present any risk or only the minimum risks compatible with its use, considered to be acceptable and consistent with or high level of protection for the safety and health of persons, taking into account in particular: - the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance; - the effect on other products, where it is reasonably foreseeable that it will be used with other products; - the presentation of the product, the labelling,	A Member State is entitled, where appropriate, proportionate to the seriousness of the risk, to ban a product that could be dangerous, or withdraw or recall a dangerous product.[986]

982 Directive 2001/37/EC, Article 3.
983 Note that the tests under Directive 2001/95/EC apply unless the risks are covered by specific legislation: Article 1.2(a).
984 Directive 2001/95/EC, Article 3.1.
985 Directive 2001/95/EC, Article 2(b).
986 Directive 2001/95/EC, Article 8.

	any warnings and instructions for its use and disposal and any other indication or information regarding the product; - the categories of consumers at risk when using the product, in particular children and the elderly.[985]	

TABLE 2 : New Approach Directives (directives providing for the CE marking)

Directive	Number of Directive, Amendment	Date of application	End of transitional period
1. Low voltage equipment	73/23/EEC 93/68/EEC	19/8/74 1/1/95	1/1/97 1/1/97
2. Simple pressure vessels	87/404/EEC 90/488/EEC 93/68/EEC	1/7/90 1/7/91 1/1/95	1/7/92 - 1/1/97
3. Toys	88/378/EEC 93/68/EEC	27/6/91 1/1/95	- 1/1/97
4. Construction products	89/106/EEC 93/68/EEC	27/6/91 1/1/95	- 1/1/97
5. Electromagnetic compatibility	89/336/EEC 92/31/EEC 93/68/EEC (98/13/EC)	1/1/92 28/10/92 1/1/95 6/11/92	31/12/95 - 1/1/97 -
6. Machinery	98/37/EC 98/79/EC	1/1/93 1/1/93 1/1/95 1/1/95 7/6/00	31/12/94 31/12/94 31/12/96 1/1/97 -
7. Personal protective equipment	89/686/EEC 93/68/EEC 93/95/EEC 96/58/EEC	1/7/92 1/1/95 29/1/94 1/1/97	30/6/95 1/1/97 - -
8. Non-automatic weighing instruments	90/384/EEC 93/68/EEC	1/1/93 1/1/95	31/12/02 1/1/97
9. Active implantable medical devices	90/385/EEC 93/42/EEC 93/68/EEC	1/1/93 1/1/95 1/1/95	31/12/94 14/6/98 1/1/97
10. Gas appliances	90/396/EEC 93/68/EEC	1/1/92 1/1/95	31/12/95 1/1/97
11. Hot water boilers	92/42/EEC 93/68/EEC	1/1/94 1/1/95	31/12/97 1/1/97
12. Civil explosives	93/15/EEC	1/1/95	31/12/02
13. Medical devices	93/42/EEC 98/79/EC 2000/70/EC 2001/104/EC	1/1/95 7/6/00 13/6/02 13/6/02	14/6/98 30/6/01 13/12/05 (placing on to market) 13/12/07 (putting into service) 10/1/07 (placing on to market) 10/1/09 (putting into service)
14. Potentially explosive atmospheres	94/9/EC	1/3/96	30/6/03

Directive	Number of Directive, Amendment	Date of application	End of transitional period
15. Recreational craft	94/25/EC 2003/44/EC	16/6/96	16/6/98
16. Lifts	95/16/EC	1/7/97	30/6/99
17. Refrigeration appliances	96/57EC	3/9/99	-
18. Pressure equipment	97/23/EC	29/11/99	29/5/02
19. In vitro diagnostic medical devices	98/79/EC	7/6/00	7/12/03 7/12/05
20. Radio and telecommunications terminal equipment	99/5/EC	8/4/00	7/4/00 7/4/01
21. Cableway installations	2000/9/EC	3/5/02	3/5/04
22. Noise Emission	2000/14/EC	3/1/02 (but 3/1/06 for stage II power levels in article 12)	-
23. Fluorescent lighting	2000/55/EC	21/5/2002 (21/11/05 - second phase for input power for ballast lamp circuits in accordance with Annex IV)	-

Directives based on the principles of the New Approach or the Global Approach, but which do not provide for the CE marking

Directive	Number of Directive	Date of application	End of transitional period
1. Packaging and packaging waste	94/62/EC	30/6/96	31/12/99
2. High speed rail systems	96/48/EC	8/4/99	-
3. Marine equipment	96/98/EC 98/85/EC 2001/53/EC 2002/75/EC 2002/84/EC	1/1/99 30/4/99 17/8/01 22/3/03 23/11/03	- - - - -
4. Transportable pressure equipment	99/36/EC 2002/50/EC	1/7/2001 (1/7/2003 in the case of Article 18) 27/6/2002	1/7/2003 -
5. Conventional rail system	2001/16/EC	20/4/03	-

Proposals for directives based on the principles of the New Approach or the Global Approach

Draft Directive	Number of Proposal, Amendment
1. Articles of precious metal	COM/93/322 final COM/94/267 final
2. Marking of packaging	COM/96/191 final
3. Measuring instruments	COM/2000/566 final COM/2002/37 final

List of New Approach directives can be found at:
http://europa.eu.int/comm/enterprise/newapproach/index.htm

Directives based on the principles of the New Approach or the Global Approach, but which do not provide for the CE marking

Directive	Number of Directive	Date of application	End of transitional period
1. Packaging and packaging waste	94/62/EC	30/6/96	31/12/99
2. High speed rail systems	96/48/EC	8/4/99	
3. Marine equipment	96/98/EC	1/1/99	

Proposals for directives based on the principles of the New Approach or the Global Approach

Draft Directive	Number of Proposal, Amendment
1. Articles of precious metal	COM/93/322 final COM/94/267 final
2. Cableway installations designed to carry passengers	COM/93/646 final
3. Marking of packaging	COM/96/191 final
4. Noise emission	COM/98/46 final

Modules in selected New Approach Technical Directives

Directive	Modules*							
	A	B	C	D	E	F	G	H
73/23 low voltage	IV							
76/117 electrical equipment for use in potentially explosive atmospheres		[3]				[3]	9	
84/528 lifting and mechanical handling appliances	8	9					8	
84/529 electrically operated lifts		3						
87/404 simple pressure vessels		10	12	3		11		
88/378 toy safety	3	3	3					
89/336 electromagnetic compatibility	3							
89/392 machinery	II	VI	3					
89/686 personal protective equipment	3	3	11. A	11. B				
90/384 non-automatic weighing instruments		II.1		II. 2		II.3	II. 4	
90/385 active implantable medical devices		III		V		IV		II
90/396 appliances burning gaseous fuels		II.1	II. 2	II. 3	II. 4	II.5	II. 6	
93/42 medical devices	VI I	III		V	VI	IV		II

* Roman numerals are references to Annexes in the relevant Directive. Arabic numerals are to Articles in Directives.

TABLE 3: Generalised safety requirements in New Approach essential requirements

[The essential words are emphasised]

Product	General essential requirement re safety	Directive: para (usually in Annex I)
Appliances burning gaseous fuels	Appliance must be do designed and built as to *operate safely* and *present no danger* to persons, domestic animals or property when normally used (as defined in article 1.4)	90/396/EEC, 1.1
Construction products	[The product, where included in] construction work must be designed and built in such a way that it does *not present unacceptable risks* of accidents in service or operation such as slipping, falling, burns, electrocution, injury from explosion. [Further requirements on mechanical resistance and stability, safety in case of fire, and hygiene, health and the environment.]	93/68/EEC, 4
EMC	The maximum electromagnetic disturbance generated by the apparatus shall be such as not to hinder the use of in particular the following apparatus ...[987]	89/33b/EEC
Lifts	The means of suspension and/or support of the car, its attachments and any terminal parts thereof must be selected and designed so as to ensure an *adequate level of overall safety* and to minimise the risk of the car falling ... The lift must be designed and constructed to prevent the risk of crushing when the car is in one of its extreme positions. [Other requirements on specific risks are specified.]	95/16/EC 1.3, 2.2
Low voltage	The electrical equipment, together with its component parts should be made in such a way as to ensure that it can be *safely* and properly *assembled and connected.* The electrical equipment should be so designed and manufactured as to ensure that	73/23/EEC.1

[987] Note that this is a utility not safety test.

	protection against the hazards [specified] *is assured* providing that the equipment is used in applications for which it was made and is adequately maintained.	
Machinery	The *aim* of measures taken must be to *eliminate any risk* of accident throughout the foreseeable lifetime of the machinery, including the phases of assembly and dismantling, even where risks of accident arise from foreseeable abnormal situations.	98/37/EC, 1.22
Medical devices	The devices must be designed and manufactured in such a way that when used under the conditions and for the purposes intended, they *will not compromise the clinical condition or the safety* of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	93/42/EEC,1.
Personal and protective equipment	PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the *user can perform* the risk-related activity *normally* whilst enjoying appropriate protection of the highest possible level. The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would *prevent its effective use* during the period of exposure to the risk or normal performance of the activity.[988]	89/686/EEC, 1.1.1, 1.1.2.1
Pressure equipment	Pressure equipment must be designed, manufactured and checked, and if applicable equipped and installed, in such a way as to ensure its *safety* when put into service in accordance with the manufacturer's instruction, or in reasonably	97/23/EC, 1.1

[988] This test is based on utility rather than safety

	foreseeable conditions.	
Recreational craft	[No general requirement. Requirements refer to specific risks including integrity and structural requirements, handling characteristics and installation requirements.]	94/25/EC.
Simple Pressure Vessels	[No general requirement. Essential safety requirements" are under the headings: materials, vessel design, manufacturing process.]	87/404/EC
Toys	The user of toys as well as third parties must be *protected against health hazards and risk of physical injury* when used as intended or in a foreseeable way, bearing in mind the normal behaviour of children ...	88/378/EEC,1

TABLE 4: Existence of legal requirements concerning pre-marketing procedures

Procedure	Medicines	New Approach	Biocides	Cosmetics	GPS
A. Collection of information					
- who generates?	(✓)	X	X	X	X
- what information?	✓	(✓)	✓	(✓)	X
- who has responsibility?	✓	✓	X	✓	✓
B. What evaluation criteria?	✓	✓	✓	(✓)	✓
C. Who decides?	✓	✓	✓	✓	✓
D. What evaluation process?	X	✓	✓	(✓)	X
E. What formalities?	✓	✓	(✓)	X	X

Key: ✓= requirements are specified; X = no requirements specified; (✓) = partial requirements specified or implied.

TABLE 5: Information Requirements

Product	Selected particulars
medicinal products	(1) Particulars to appear on packaging, including a special warning if this is necessary, and the expiry date.[989] (2) obligatory package leaflet, to include many particulars, including dosage, frequency of administration, duration of treatment, contra-indications, appropriate precautions for use, interaction with other products, special warnings, actions on overdose, description of undesirable effects that can occur on normal use.[990]
medical devices	Every device must be accompanied by the information needed to use it safely, taking account of the training and knowledge of potential users. Label and instructions for use must include particulars including special handling conditions, special operating instructions, any warnings and/or precautions to take, use-by date.[991]
machinery	Instructions for putting into service, safe use and maintenance, and where necessary training.[992]
toys	Toys must be accompanied by appropriate clearly legible warnings. Specific warnings and indications of precautions are specified for certain categories, e.g. "Not suitable for children under 36 months", slides, functional toys ("warning: to be used under the direct supervision of an adult"), toys containing inherently dangerous substances or preparations, chemical toys ("warning: for children under x years of age only. For use under adult supervision."), states and skateboards ("warning: protective equipment should be worn"), toys intended for use in water ("warning! Only to be used in water in which the child is within its depth and under supervision.")[993]
pressure equipment	Instructions for the user to contain all the necessary safety information relating to mounting, putting into service, use, maintenance; if appropriate refer to hazards

989 Directive 2001/83/EC, article 54. Recital 40 to that Directive states: "The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information".

990 Ibid, article 59.

991 Directive 93/42/EEC, Annex I, para 13. The full list is more extensive.

992 Directive 98/37/EEC, Annex I, para 1.7.4. Opinion of the Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC' 2001/C 311/01, OJ No C 311/1, 7.11.2001 para 4.8.9.1 criticised the absence a requirement covering instructions for use.

993 Directive 88/378/EEC, Annex IV.

Product	Selected particulars
	arising from misuse that is known or clearly foreseen, and design features re stress and stability.[994]
simple pressure vessel	Instructions must include maximum working pressure and temperature, minimum temperature, capacity, maintenance and installation requirements for vessel safety.
personal protective equipment	All relevant information on storage, use, cleaning maintenance, servicing, disinfection, performance and obsolescence deadline.[995]
low voltage equipment	The essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made.[996]
lifts	Instruction manual so that assembly, connection, adjustment and maintenance can be carried out effectively and without danger.[997]
recreational craft	Owner's manual should draw particular attention to risks of fire and flooding, maximum recommended load, and handling characteristics.[998]
EMC	The information required to enable use in accordance with the intended purpose of the apparatus must be contained in the instructions.[999]
cosmetics	Container and packaging must show date of minimum durability, particular precautions to be observed in use (including those specified in the Directive's Annexes), batch number, function, list of ingredients.[1000]
tobacco	Packet to show tar, nicotine and carbon monoxide yields, general warnings (e.g. "Smoking kills") and an additional warning (e.g. "Smoking is highly addictive, don't start").[1001]

994 Directive 97/23/EC, Annex II.

995 Directive 89/686/EEC, Annex II, para 1.4.

996 Directive 73/23/EEC, Annex I, para 1.

997 Directive 95/16/EC, Annex I, para 6.

998 Directive 94/25/EC.

999 Directive 89/336/EEC, Annex III. This is expanded in the Proposal for a revised Directive , COM (2002) 759, 23.12.2002, Annex I, part 2, to include information on any specific precautions that have to be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that it is in conformity with the protection requirements.

1000 Directive 76/768/EEC, article 6.

1001 Directive 2001/37/EC, article 5.

Product	Selected particulars
biocides	Identity of active substances, use, directions for use, dose rate, batch code, adverse side effects, directions for first aid, "Read attached instructions before use" on any leaflet, directions for safe disposal, expiry date, time for biocidal effect, categories of users to whom use is restricted.[1002]
general consumer products	provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.[1003]

1002 Directive 98/8/EC, article 20.

1003 Directive 2001/95/EC, article 5.

TABLE 6: Mandated health warnings for tobacco products

Health Warnings	Location
General warning "Smoking kills" or "Smoking can kill"	The most visible surface of the unit packet, and any outside packaging used in retail sale
Additional warnings taken from the following list, rotated in such a way as to guarantee their regular appearance: 1. Smokers die younger. 2. Smoking clogs the arteries and causes heart attacks and strokes. 3. Smoking causes fatal lung cancer. 4. Smoking when pregnant harms your baby. 5. Protect children: don't make them breathe your smoke. 6. Your doctor or your pharmacist can help you stop smoking. 7. Smoking is highly addictive, don't start. 8. Stopping smoking reduces the risk of fatal heart and lung diseases. 9. Smoking can cause a slow and painful death. 10. Get help to stop smoking: (telephone/ postal address/consult your doctor/pharmacist). 11. Smoking may reduce the blood flow and causes impotence. 12. Smoking causes ageing of the skin. 13. Smoking can damage the sperm and decreases fertility. 14. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.	The other most visible surface of the unit packet, and any outside packaging used in retail sale.
Permitted tobacco **products for oral use** and smokeless tobacco products are required to carry the warning: "This tobacco product can damage your health and is addictive" printed on the most visible surface of the unit packet, and any outside packaging used in retail sale.	

TABLE 7: Existence of legal requirements concerning manufacturers' post-marketing obligations

Procedure	Medicines	New Approach	Biocides	Cosmetics	GPS
Keeping technical documentation					
- what information	✓	✓	✓	✓	✖
- who keeps?	✓	(✓)	✓	✓	✖
- how long?	✓	✓ some	(✓)	✖	✖
Collecting new information	✓	✓	(✓)	✓	(✓)
Investigation	✓	✖	✖	✖	✓
Assessment	(✓)	✖	✖	✖	(✓)
Reporting	✓	✓ med dev ✖ others	✓	✖	✓
Decision					
- what criteria?	✖	✖	✖	✖	✖
- what action	✖	✖	✖	✖	✖
Implementing action	✖	✖	✖	✖	✓

Key: ✓ = Specified; ✖ = unspecified; (✓) = Implicit or partially specified

TABLE 8: Time periods for document retention

Type	Period	Ref: Directive, article
Medicines	Toxicology: national requirements. Clinical data: 15 years after the trail for patient identification codes; 5 years after product no longer authorised for Final Report; duration of product's authorisation for other data	99/11, 99/12 2001/83, Annex I Part 4.
Medical devices	5 years after the last product was manufactured.	93/42, Annex II, 6.1; Annex VII, 2
Machinery	10 years after date of manufacture of the machine, or of last unit produced	98/37, Annex V para 4(2)
Pressure vessels	10 years after the last equipment has been manufactured	97/23, Annex III Module A only
Lifts	10 years after the last safety component was manufactured	95/10, Annexes V, VIII [different wording for Annexes VIII, IX, X, XI, the last two requiring declaration of conformity only].
Cosmetics	Not specified but implicit that for the period that the product is on the market.	
Biocides	Authority retains dossier; implicitly for at least period that the product is on the market.	98/8, 6
GPS	Not specified but the continuous monitoring obligation implies for lifetime of the product.	2001/95, 5

TABLE 9: Summary of the actors who make ultimate decisions on product safety

Sector	Pre-marketing	Post-marketing
Medicines - centralised	Commission, with advice of EMEA/CPMP.	Commission, with advice.
- mutual recognition	Member State, if single State involved. Under mutual recognition procedure, Member States, or if no agreement CPMP.	Member State. Where divergence, Commission and Committee.
New Approach	Manufacturer, sometimes with approval of Notified Body.	Manufacturer; Member State; Commission and Member States.
Cosmetics	Manufacturer. Committee bans or approves certain substances.	Member State.
Biocides	First Member State (mutual recognition by others, or Commission and Committee if no agreement). Substances' list approved by Member States and Commission.	Member State
GPS	Manufacturer	Member State

Note: In cases of disagreement, the Member States meet in Committee chaired by the Commission.

TABLE 10: Selected Community level trade associations and consumer associations

Union of Industrial and Employers' Confederations of Europe (UNICE)
European Federation of Pharmaceutical Industries and Associations (EFPIA)
Liaison Group of the European Mechanical, Electrical, Electronic and Metalworking Industries (ORGALIME)
European Automobile Manufacturers Association (ACEA)
European Confederation of Medical Devices Associations (EUCOMED)
European Diagnostic Manufacturers Association (EDMA)
Comité Européen des Assurances (CEA)
The Confederation of European Community Cigarette Manufacturers (CECCM)
Confederation of the Food and Drink Industries of the EU (CIAA)
The European Cosmetic Toiletry and Perfumery Association (COLIPA)
European Committee of Domestic Equipment Manufacturers (CECED)
European Union of Consumers' Representatives (BEUC)
The European Association for consumers' representation in standardisation (ANEC)

TABLE 11: Committees established under selected Directives

Committee	Responsibility
Enterprise DG	
Committee on Standards and Technical Regulations[1004]	assist the Commission [where harmonised standards do not entirely meet the essential requirements] re active implantable medical devices,[1005] medical devices,[1006] in vitro diagnostic medical devices,[1007] machinery,[1008] EMC,[1009] PPE,[1010] non-automatic weighing instruments,[1011] simple pressure vessels,[1012] pressure equipment,[1013] toys,[1014] lifts,[1015] recreational craft.[1016] Interface with European Standards Organisations.
Standing Committee on Medicinal Products for Human Use[1017]	providing an opinion to the Commission on draft measures to be taken on grant of marketing authorisations or their variation, or on manufacturing authorisations, or adaptation of the pharmacovigilance system to scientific and technical progress.[1018]
Advisory Committee on the approximation to the laws of Member States relating to Medical Devices[1019]	assist the Commission, and examine any question connected with implementation of the Directive.[1020]
Standing Committee on Machinery	any matter relating to the implementation and practical application of the Directive.[1021]
Advisory Committee on Machinery	
Standing Committee established by Directive 89/686/EEC, article 6(2)	any matter to which the implementation and practical application of the Directives on PPE[1022] gives rise.

Established under Directive 83/189/EEC, article 5: note that this procedure does not apply to all Directives, such as LVD, pressure vessels, toys. See J Falke, "Comitology: From Small Councils to Complex Networks" in M Andenas and A Türk (eds), *Delegated Legislation and the Role of Committees in the EC* (Kluwer, 2000).

1005 Directive 90/385/EEC, article 6.1.

1006 Directive 93/42/EEC, article 6.

1007 Directive 98/79/EC, article 6.

1008 Directive 98/37/EC, article 6.1.

1009 Directive 89/336/EEC, article 8.

1010 Directive 89/686/EEC, article 6.1.

1011 Directive 90/384/EEC, article 6.

1012 Directive 87/404/EEC, article 6.

1013 Directive 97/23/EC, article 6.

1014 Directive 88/378/EEC, article 6.

1015 Directive 95/16/EC, article 6.1.

1016 Directive 94/25/EC, article 6.1.

1017 Regulation (EEC) No 2309/93, articles 72 and 73.

1018 Regulation (EEC) No 2309/93, articles 10, 15, 18 and 26.

1019 Established under Directive 90/385/EC, article 6(2).

1020 Directives 90/385/EEC, article 6.2; 93/42/EEC, article 7; 98/79/EC, article 7.

1021 Established under Directive 89/392/EEC, article 6(2), now Directive 98/37/EC, article 6.2.

Committee	Responsibility
Standing Committee on the approximation of the laws of Member States concerning Pressure Equipment	assist the Commission.[1023]
Standing Committee on Lifts	assist the Commission.[1024]
Standing Committee on recreational craft	assist the Commission.[1025]
Standing Committee on Construction	examine any question posed by the implementation and the practical implementation of the Directive.[1026]
ATEX Standing Committee (explosive atmospheres)	Assist the Commission.[1027]
Telecommuncations Conformity Assessment and Market Surveillance Committee (TCAM)	Assist the Commission.[1028]
Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector (CATP/COSM)	[no function specified beyond its name].[1029]
Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers[1030]	referred to obliquely as having functions of consultation on (a) Commission draft measures to postpone implementation of changes after delay in developing methods to replace animal testing, (b) amendments necessary for the adaptation to technical progress of the Annexes, (c) the banning or inclusion of substances authorised by Member States in the permitted list.[1031]
Standing Committee on Biocidal Products	assist the Commission.[1032]
Internal Market DG	
Internal Market Advisory Committee	consultation to the Commission on any practical problem

1022 Directive 89/686/EEC, article 6.2.
1023 Directive 97/23/EC, article 7.2.
1024 Directive 95/16/EC, article 6.3.
1025 Directive 94/25/EC, article 6.3.
1026 Established under Directive 89/106/EEC, Article 19.
1027 Established under Directive 94/9/EC, Article 6(3).
1028 Established under Directive 1999/5/EC, Article 13.
1029 Directive 76/768/EEC, article 9.
1030 Commission Decision 97/579/EC, replacing the Scientific Committee on Cosmetology established by Commission Decision 78/45/EEC.
1031 Directive 76/768/EEC, articles 4.1, 8 and 8a.
1032 Directive 98/8/EC, article 28.

Committee	Responsibility
(IMAC)	concerning the functioning of the internal market, other than those covered otherwise.[1033]
Committee on checks for conformity with the rules on product safety in the case of products imported from third countries.	Assist the Commission.[1034]
Health and Consumer Protection DG	
Committee on product safety emergencies	Assist the Commission.[1035]
Scientific Steering Committee in the field of consumer health and food safety.[1036]	assist the Commission to obtain the best scientific advice available on matters relating to consumer health. Coordinate the work of the scientific committees set up by the Commission to address matters of consumer health.
Scientific Committee on Medicinal Products and Medical Devices.[1037]	Scientific and technical questions relating to Community legislation concerning medicaments for human and veterinary use (without prejudice to the specific competencies given to the CPMP), medical materials and equipment.
Committee on Tobacco	assist the Commission.[1038]
Regulatory Committee on Consumer Product Safety	matters relating to standards and emergency measures.[1039]
Advisory Committee on Consumer Product Safety	assist the Commission.[1040]
AGENCIES	
Committee on Proprietary Products (CPMP)[1041]	formulating the opinion of the Agency on any question concerning the admissibility of the files submitted in accordance with the centralised procedure, the granting, variation, suspension or withdrawal of an authorisation to place a medicinal product for human use on the market

1033 Commission Decision 93/72/EEC.
1034 Regulation 339/93, Article 9.
1035 Directive 92/59/EEC, Article 10.
1036 Commission Decision 97/404/EC. See J Falke "Comitology: From Small Councils to Complex Networks" in M Andenas and A Türk (eds), *Delegated Legislation and the Role of Committees in the EC* (Kluwer, 2000).
1037 Commission Decision 97/579/EC.
1038 Directive 2001/37/EC, article 10.
1039 Directive 2001/95/EC, articles 4, 13, 14.1.
1040 Directive 2001/95/EC, articles 11, 12, 15.1.

Committee	Responsibility
	and pharmacovigilance.[1042]
Committee for Orphan Medicinal Products (COMP)[1043]	to examine any application for the designation of a medicinal product as an orphan medicinal product which is submitted to it in accordance with this Regulation; to advise the Commission on the establishment and development of a policy on orphan medicinal products for the European Union; to assist the Commission in liaising internationally on matters relating to orphan medicinal products, and in liaising with patient support groups; to assist the Commission in drawing up detailed guidelines.

1041 Established in 1973 under Directive 75/319/EEC, article 8.

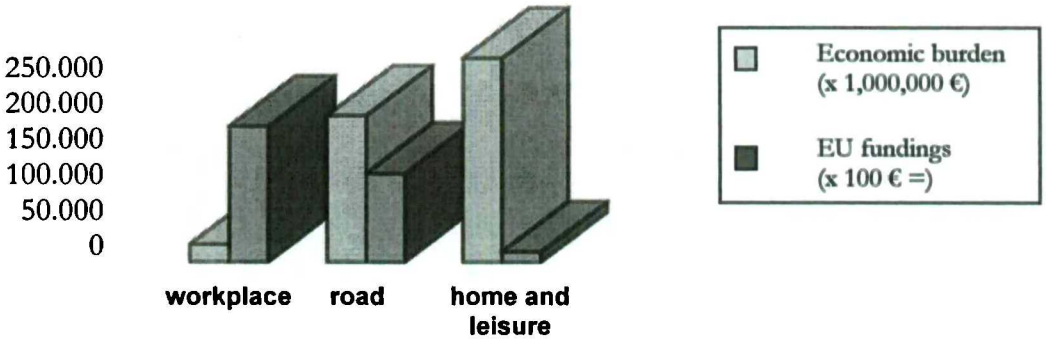
1042 Regulation (EEC) No 2309/93, article 5 for the centralised procedure and Directive 2001/83/EC< article 2, for the mutual recognition procedure.

1043 Regulation (EC) No 141/2000, Article 4.

TABLE 12: The price of a life

Cost of saving one year of one person's life in 1993 $	
Passing laws to make seat-belt use mandatory	69
Sickle-cell anaemia screening for black new-borns	240
Mammography for women aged 50	810
Pneumonia vaccination for people aged over 65	2,000
Giving advice on stopping smoking to people who smoke more than one packet a day	9,800
Putting men aged 30 on a low-cholesterol diet	19,000
Regular leisure-time physical activity, such as jogging for men aged 35	38,000
Making pedestrians and cyclists more visible	73,000
Installing air-bags (rather than manual lap belts) in cars	120,000
Installing arsenic emission-control at glass manufacturing plants	51,000,000
Setting radiation emission standards for nuclear-power plants	180,000,000
Installing benzene emission control at rubber-tyre manufacturing plants	20,000,000,000

Figure 1: Comparison of the economic burden and level of EU funding for the three major injury categories



From: *Priorities for Consumer Safety in the European Union: Agenda for Action*, European Consumer Safety Association, 2001

APPENDIX 1: THE PHARMACOVIGILANCE SYSTEM

Rationale and purposes of the system

It is positively anticipated that use of medicinal products will be associated with some injuries in view of the fact that they are not intended to be benign, unlike many other consumer products, but to have pharmacological effect. Data collected from use of medicinal products shows that each has an unique safety profile, in that a particular range of adverse drug reactions (ADRs) is associated with its use. Further, the assessment of the product's safety which is undertaken at the pre-marketing stage is merely provisional and must be continuously reassessed throughout the lifetime of marketing the product. By the time that a medicine is licenced, it is possible that only the more common and pharmacologically predictable ADRs will be known. For the entire duration of a drug's life span, continued safety surveillance is required to identify the rare, more serious ADRs and to study the safety profile in selected populations of patients (e.g. children or those with renal failure). The purpose is to identify new adverse reactions, to constantly reassess the safety profile through re-evaluation of a product's benefit-risk ratio,.[1044] and to attempt to quantify the risk to the patient.

The purpose of the Pharmacovigilance System is to identify the ADR profile of each product. The essential features of the Community' Pharmacovigilance System are:

(a) the holder of a marketing authorisation is required to have a "qualified person" responsible for pharmacovigilance, who is obliged to establish and maintain the company's pharmacovigilance, that records all suspected adverse reactions which are reported to the company, and to prepare adverse reaction reports for the competent authorities and respond to the authorities' enquiries: any new scientific information must be assessed and acted on, such as by applying to the authorities for variations to the product's summary of product characteristics or by withdrawing the product from the market;

(b) the holder of a manufacturing authorisation must have qualifying staff, give prior notice to the competent authority of any changes he may wish to make in his approved particulars on facilities and the product, permit the authority access to his premises at any time, and comply with the principles and guidelines of good manufacturing practice for medicinal products;[1045]

(c) the holder of a wholesale distribution authorisation has related obligations;

(d) Member State competent authorities, the EMEA and the Commission are required to operate appropriate systems so as to share specified information between themselves and evaluate it, with powers to take action such as to withdraw products from the market.

1044 Ibid, para 1.6. It is said that benefit-risk assessment should be carried out separately for each indication.

1045 Directive 2001/83/EC, Title IV.

A summary of the system

Extensive guidance documents are promulgated by the European Commission or EMEA,[1046] which require as follows:

(a) all relevant information should be shared between the competent authorities and the marketing authorisation holder; this requires extensive exchange of information between the marketing authorisation holder, the Member States and the Agency as well as procedures to avoid duplication, maintain confidentiality and ensure the quality of the systems and data;[1047]

(b) the marketing authorisation holder must ensure that it has an appropriate system of pharmacovigilance in place in order to assure responsibility and liability for its products on the market and to ensure that appropriate action can be taken, when necessary;[1048]

(c) the responsibilities of the qualified person are generally as set out in the legislation, noted above;

(d) marketing authorisation holders should ensure that all information relevant to the balance of benefits and risks of a medicinal product is reported to the authorities/Agency fully and promptly;[1049]

(e) when marketing authorisation holders are involved in relationships, including those that are contractual, arrangements for meeting pharmacovigilance obligations should be clearly specified in writing to the competent authority at the time that the authorisation is granted, and subsequently when any changes are proposed;[1050]

(f) the responsibilities for pharmacovigilance rest, for nationally authorised and mutual recognition products, with the competent authorities of *all* the member states in which authorisations are held, although the reference state will normally take the lead and coordinate with the marketing authorisation holder, and, for centrally authorised products, with the European Commission as competent authority, although the pre-authorisation

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1046 Including *Notice to Marketing Authorization Holders – Pharmacovigilance Guidelines No PhVWP/108/99*, European Agency for the Evaluation of Medicinal Products ("EMEA") *Conduct of Pharmacovigilance for Contrally Authorised Products*, EMEA, (April 1997); *Conduct of Pharmacovigilance for Medicinal Products Authorised through the Mutual Recognition Procedure*, EMEA, (June 1997); *Topic E1A Population Exposure: The Extent of Population Exposure to Assess Clinical Safety*, International Conference on Harmonisation ("ICH"); *Topic E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*, ICH; *Topic E2B(M) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports*, ICH; *Topic E2C Clinical Data Safety Management: Periodic Safety Update Reports for Marketed Drugs*, ICH; *Note for Guidance on Electronic Exchange of Pharmacovigilance Information for Human and Veterinary Medicinal Products in the European Union*, Committee for Proprietary Medicinal Products (August 1999); *Joint Pharmacovigilance Plan for the Implementation of the ICH E2B M1 and M2 Requirements Related to the Electronic Transmission of Individual Case Safety Reports in the Community*, Committee on Proprietary Medicinal Products.

1047 See Notice to Marketing Authorisation Holders, above, para 1.1.

1048 Ibid, para 1.1.1.

1049 Ibid.

1050 Ibid.

rapporteur state takes the lead in pharmacovigilance, and the Agency will co-ordinate the supervision of products;[1051]

(g) the Agency's scientific committee, the CPMP, aided by its Pharmacovigilance Working Party (PhVWP) is responsible for evaluating evidence and formulating Opinions on emerging drug safety issues with centrally authorised products, based on the rapporteur's assessment report;[1052]

(h) marketing authorisation holders are expected to validate and follow-up all serious reactions reported by them to the authorities;[1053]

(i) there are procedures, formats and time limits for reporting different kinds of information: all spontaneous case reports of serious suspected adverse reactions[1054] are to be reported on an expedited basis; case reports from worldwide literature, which the marketing authorisation holder is expected to screen; reports from post-authorisation studies;[1055]

(j) periodic safety update reports (PUSRs) are to be submitted, with a prescribed format, the object of which is to establish whether information recorded during the reporting period is in accordance with previous knowledge on the product's safety and to indicate whether changes should be made: these are made normally at 6-monthly intervals for the first two years after authorisation, then annually for 2 years, at the first renewal, then 5-yearly at renewal;[1056]

(k) post-authorisation safety studies may be required for the purpose of identifying previously unrecognised safety issues (hypothesis-generation), investigating possible hazards) hypothesis-testing in order to substantiate a causal association) or confirming the expected safety profile of a product under marketed conditions, quantifying established adverse reactions or identifying risk factors;[1057]

Once a report of a serious ADR has been made, the Guidelines require that it be investigated and an assessment made of whether the event was caused by the drug, some other cause, an interaction between the drug and another drug or substance, or part of the underlying disease state.[1058] The objective is then to determine whether the data constitutes a "signal", i.e. a disproportionate increase

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1051 Ibid, paras 1.1.2 and 1.1.3.

1052 Ibid, para 1.1.3.4.

1053 Ibid, para 1.2.1. "A reaction is suspected if either the reporting health-care professional or the marketing authorisation holder believes there is a possible causal relationship between it and the drug in question. Spontaneous reports of suspected adverse drug reactions received from health-care professionals should be reported even if the marketing authorisation holder does not agree with the reporter's assessment of a possible causal association, or if the reporter has not provided a causal assessment." This drafting is one of a number of instances that leave an element of subjectivity which may be give rise to enforceability issues if non-compliance occurred, but its enforceability as guidelines is in any event unclear. Strict legal enforceability may not, however, be a major issue, since loss of confidence in a marketing authorisation holder by the authorities or professional community or public may have greater impact.

1054 A serious adverse reaction is one which results in death, is life-threatening, requires inpatient hospitalisation, or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect. Guidelines: 3. Terminology.

1055 Ibid, para 1.2.2.1.

1056 Ibid, para 1.4.

1057 Ibid, para 1.5.

1058 Notice to Marketing Authorisation Holders, para 1.2.1: the marketing authorisation holder "is expected to validate and follow-up" all serious ADR reports.

in the number of reactions known to be connected with use of a particular drug. If the ADR is thought to be drug related, all relevant information will then be monitored and assessed to try and determine the incidence of the hazard and its severity (i.e. the risk) and, hence, whether the risk/benefit balance has changed and whether any action might be appropriate. The position will be closely discussed between the competent authorities and the marketing authorisation holder or manufacturer.

The role of the authorities

The Guidelines state that each Member State must establish a national pharmacovigilance system for the collection and evaluation of information, and should take all appropriate measures to encourage physicians and other healthcare professionals to report suspected adverse reactions to the competent authorities,[1059] and oblige marketing authorisation holders systematically to collect information on risks related to their products and to transmit those to the competent authorities.[1060] The national systems for collecting ADR data vary considerably over who can make reports and whether this is voluntary or compulsory. Information is exchanged via a secure email system, EudraNet.[1061] All member states are also to collaborate with the World Health Organisation Collaborating Centre for International Drug Monitoring,[1062] which has a database established in Uppsala. For products authorised under the central system the pre-authorisation rapporteur takes the lead in pharmacovigilance, and the Agency provides co-ordination of supervision with the marketing authorisation holder, with scientific advice from the CPMP and its Pharmacovigilance Working Party (PhVWP), whereas for products under the mutual recognition system the reference member state takes the lead and is responsible for co-ordination of communications with the marketing authorisation holder.

Data entered into pharmacovigilance databases is used for to identify case aggregates or trends indicating a "signal", i.e. a specific effect caused by a product that can be identified. Information is communicated between the member state authorities, the Commission and the Agency by one of two procedures, the Rapid Alert System (RAS) and the Non-Urgent Information System (NUIS).

1059 This is also an obligation under Directive 2001/83/EC, article 101.

1060 Procedure for Competent Authorities on the undertaking of pharmacovigilance activities, para 1.

1061 Standard Operating Procedures "EudraNet E-Mail Policy" (IT-SOP 9724.2.8) and "EudraNet Network Policy" (IT-SOP 9720.3.2).

1062 Guidelines 2.6 Principles of providing the World Health Organization with pharmacovigilance information.

APPENDIX 2: STATISTICS ON GENERAL CONSUMER PRODUCTS

The general incidence of accidents, mortality and morbidity

Injury is currently the fourth major cause of death in Europe, killing 130,000 people a year, ranking after cardiovascular diseases, cancer and respiratory diseases, but ranking first for children and adolescents.[1063] The major factors associated with the major health threats as at 1993 are shown in Table 2.1. However, Community Health Policy documents record that the overall death rate from accidents has declined since 1970.[1064]

Table 2.1: Factors implicated in disease causation

Disease	Factors
Accidents	Drunken driving, unsafe behaviour, defective or poorly designed products and services, environmental problems
Cancer	Smoking, alcohol abuse, nutrition, genetic factors, exposure to radiation and carcinogenic substances
Cardio-vascular diseases	Smoking, alcohol abuse, nutrition, genetic factors, stress, lack of exercise
Communicable diseases, including AIDS	Poor hygiene, unsafe water, unsafe sexual behaviour, drug abuse, nutrition, contaminated blood
Drug abuse	Socio-economic problems, psychological disorders, stress
Mental illness, including suicide	Socio-economic problems, genetic factors, stress
Musculo-skeletal conditions	Poor working environment, physical stress, nutrition, lack of exercise
Respiratory diseases, including asthma	Environment problems, including pollutants, smoking, genetic factors

1063 *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001). WHO concluded that the relative contribution of mortality from accidents, injury and poisoning increased from 7.4% in 1980 to 9.0% in 1990: *Atlas of mortality in Europe* (World Health Organisation, 1997), p148-149.

1064 Commission Communication on the framework for action in the field of public health, COM (93) 559 final, 24 November 1993. For further analysis, especially of particular issues for particular age groups, see Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the state of health in the European Community, COM (95) 357 final, 19.07.1995.

As Table 2.2 shows, the majority of such accidents occur in the home and leisure category: only in the other two major categories of traffic and workplace has there been a decline.[1065]

Table 2.2: Number of accidental deaths and injuries in the EU by cause

Location	Deaths	Injuries[1066]
Home and Leisure[1067]	80,000	40,000,000
Road traffic[1068]	43,000	3,500,000
Workplace[1069]	5,500	4,800,000

The mortality rate varies across EU and accession states, as shown in Table 2.3 .

Table 2.3: all ages mortality rates[1070]

State	Rate/100,000 (1993)
Estonia	176.77
Lithuania	167.8
Latvia	91.57
Romania	86.13
Hungary	69.69
Poland	59.69
Bulgaria	55.34
Slovenia	52.98
Finland	52.52

1065 *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001) stated that in Europe, deaths in the workplace fell 14% between 1994 and 1996, deaths on the road fell 27% and traffic injuries fell 11% between 1980 and 1995 despite a 50% increase in traffic volumes in that period.

1066 Quoted in *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001, adjusted for under-reporting, with Home and Leisure including only medically-treated injuries.

1067 Anon, *Measuring the burden of injuries* (European Consumer Safety Association, 1999).

1068 Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: Promoting road safety in the EU, The Programme for 1997-2001, COM (97) 131; European Transport Safety Council, 2001.

1069 European Agency for Health and Safety at the Workplace, *Annual Report*, 2001.

1070 *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001.

France	43.18
Luxembourg	42.61
Czech Republic	40.08
Portugal	40.05
Greece	38.82
Austria	35.95
Belgium	35.46
Spain	35.33
Slovak Republic	31.76
Italy	30.34
Ireland	30.02
Germany	25.42
Sweden	22.42
Denmark	19.99
Netherlands	18.87
United Kingdom	18.36
Malta	10.53

Table 2.4 sets out the risk of dying during 1989[1071] and 2000[1072] in England and Wales from various causes and Table 2.5 sets out the mortality risks from various diseases.

Table 2.4: Risk of dying in 1989 in England and Wales by cause[1073]

Cause	In 1989	Due to a given cause in 1989	In 2000

1071 Based on 1989 Mortality Statistics for England and Wales. DH2 No 16, Office of Population Censuses and Surveys: quoted by A P Fletcher and S Shaw "The safety of medicines" in J P Griffin and J O'Grady (eds), *The Textbook of Pharmaceutical Medicine*, BMJ Books, 4ed, 2002.

1072 *Financial Times*, 29 July 2000, reproduced in *Working for a Safer World: 23rd Annual Report of [Consumer Safety]*, (Department of Trade and Industry, 2000).

1073 Based on 1989 Mortality Statistics for England and Wales. DH2 No. 16, Office of Population Censuses and Surveys. From A P Fletcher and S Shaw, "The safety of medicines" in J P Griffin and J O'Grady (eds), *The Textbook of Pharmaceutical Medicine* (BMJ Books, 4ed, 2002).

Any cause	1 in 88	1 in 1	1 in 100
Disease of the circulatory system	1 in 190	1 in 2.2	
Smoking related illness			1 in 200
Neoplasm	1 in 350	1 in 4	
Accident and violence	1 in 3000	1 in 33	
Motor traffic accidents	1 in 10,000	1 in 130	1 in 10,000
Home accident			1 in 13,000
Poisoning by drugs	1 in 30,000	1 in 330	
Toxic effect of carbon monoxide	1 in 40,000	1 in 450	
Fire and flames	1 in 90,000	1 in 1000	
Poisoning by antidepressants	1 in 160,000	1 in 1899	
Homicide	1 in 180,000	1 in 2000	1 in 100,000
Air crash			1 in 200,000
Toxic effect of ethanol	1 in 420,000	1 in 4800	
Railway accidents	1 in 700,000	1 in 8000	
Poisoning by salicylates	1 in 800,000	1 in 9500	
Assault by poison	1 in 4,200,000	1 in 48,000	
Lightning strike			1 in 10 million
Any cause	2 in 88	2 in 1	

Table 2.5: Selected mortality risk levels, England and Wales 1984

Cause	Number of deaths in 1984	Probability of mortality
All causes	566,881	1.0×10^{2}
Cancers	140,101	2.8×10^{3}
Coronary heart disease	157,506	3.2×10^{3}
Strokes	14,211	2.9×10^{4}

Diabetes	6369	1.3×10^{-4}
Asthma	1764	3.5×10^{5}
Cirrhosis	2280	4.5×10^{5}
Ulcers (stomach and duodenum)	4483	9.0×10^{5}
Pregnancy	52	1.4×10^{6}
Measles	10	2.0×10^{8}
Whooping cough	1	4.0×10^{8}

These figures should be compared with figures from USA, reproduced at Tables 2.6[1074] and 2.7, the first of which concluded that the chances of being killed by an asteroid/comet impact are about the same as dying in an air accident. It is instructive to consider the references to dangerous products in these tables – and the absence of such references.

Table 2.6: Chances of dying from selected cause (USA), 1994[1075]

Causes of death	Chances
Motor vehicle accident	1 in 100
Murder	1 in 300
Fire	1 in 800
Firearms accident	1 in 2500
Asteroid/comet impact (lower limit)	1 in 3000
Electrocution	1 in 5000
Asteroid/comet impact	1 in 20,000
Passenger aircraft crash	1 in 20,000
Flood	1 in 30,000
Tornado	1 in 60,000
Venomous bite or sting	1 in 100,000
Asteroid/comet impact (upper limit)	1 in 250,000

1074 C R Chapman and D Morrison, "Impacts on the Earth by asteroids and comets: assessing the hazard", *Nature*, 1994;**367**:33-40.

1075 From A P Fletcher and S Shaw, "The safety of medicines" in J P Griffin and J O'Grady (eds), *The Textbook of Pharmaceutical Medicine* (BMJ Books, 4ed, 2002).

Fireworks accident	1 in 1 million
Food poisoning by botulism	1 in 3 million
Drinking water with EPA limit of TCE[1076]	1 in 10 million

Table 2.7: Risks estimated to increase chance of death in any year by one part in a million (USA)[1077]

Activity	Cause of death
Smoking 1.4 cigarettes	Cancer, heart disease
Drinking 0.5 litres of wine	Cirrhosis of liver
Spending 1 hour in a coal mine	Black lung disease
Spending 3 hours in a coal mine	Accident
Living 2 days in Boston or New York	Air pollution
Travelling 6 minutes by canoe	Accident
Travelling 10 miles by bicycle	Accident
Travelling 150 miles by car	Accident
Flying 1000 miles by jet	Accident
Flying 6000 miles by jet	Cancer caused by cosmic radiation
Living 2 months in average stone or brick building	Cancer caused by natural radioactivity
One chest X-ray in a good hospital	Cancer caused by radiation
Living 2 months with a cigarette smoker	Cancer, heart disease
Eating 40 tablespoons of peanut butter	Cancer caused by aflatoxin B
Drinking 30 cans of diet soda	Cancer caused by saccharin
Living 150 years within 20 miles of a nuclear plant	Cancer caused by radiation

Figures on accidents associated with consumer products are discussed at Appendix 2. The kinds of home accidents in the United Kingdom that equate to particular odds of death in 2000 are shown in Table 2.8:[1078] probabilities alter depending on age.

1076 EPA, Environmental Protection Agency; TCE, trichloroethylene.

1077 From A P Fletcher and S Shaw, "The safety of medicines" in J P Griffin and J O'Grady (eds), *The Textbook of Pharmaceutical Medicine* (BMJ Books, 4ed, 2002).

Table 2.8: Probabilities of death from home accidents and other causes in UK

Probability	Death	Accident
1 in 100	Any cause	Striking/colliding with a stationary object
1 in 200	Smoking-related illness	Cut/tear (sharp)
1 in 10,000	Road accident	Electric/radiation
1 in 13,000	Home accident	
1 in 100,000	Murder	Struck/explosion
1 in 200,000	Air crash	Electric blanket or cleaning fluid

Statistics on unsafe products notified in Community mechanisms

How safe are products? Data on the safety of products in use is difficult to come by. Some statistics are available from notifications within the Community's systems, from national data on accidents, prosecutions and recalls. However, the influence of counterfeiting must be taken into account.

The number of notifications recorded on the RAPEX system for serious and immediate risks[1079] during the period 1996 to 2000 is set out in Table 2.9.

Table 2.9: RAPEX notifications[1080]

	1996	1997	1998	1999	2000
Dangerous imitations	4	0	2	7	4
GPS	53	55	71	119	100
Total	57	73	80	139[1081]	142
Voluntary measures	0	18	7	13	38

1078 *Working for a safer world: 23rd Annual Report on consumer safety*, (Department of Trade and Industry, 2000). There were 2.8 million home accidents and 3.1 million leisure accidents in 1999 from whatever cause.

1079 A problem with the system was to achieve uniform understanding of what was meant by serious and immediate danger. The Commission noted that the concept of safety is a changing one and products which were considered safe ten years before were now deemed to be unsafe. It was decided not to attempt to give a more precise definition but to tackle the issue by means of guidelines issued by the Consultative Committee.

1080 Annual Reports of and personal communications with the Commission's Directorate-General on Health and Consumer Protection.

1081 The main categories of notifications were laser pointers and toys.

On relation to RAPEX notifications, between March 1985 and 31 December 1987:

- of the non-food cases, 50% were electrical goods, but of 18 notifications received only 1 directly concerned children. However, the predominance of electrical goods might have been due to the existence of a specific requirement to test imported electrical goods to assess conformity with the "low voltage" directive.

- of the non-food notifications, about 50% originated in non-Community countries.

It is to be expected that a new system, especially one that involves a very large geographical area and the involvement of a number of operative entities that are each in a different stage of evolution and with different experience, will operate slowly and inconsistently, and that it will take time for the level of valid notifications to stabilise. This indicated by the statistics. For example, in 1990 there were only 16 notifications, but this rose to 96 in 1991, albeit with a patchy response: (Belgium 49, Spain 11, United Kingdom 19 but none from other States. Only 182 notifications had been received from Member States in the first 4 years of the GPSD system (1995-8) and reactions were made by Member States in only 50% of 47 notifications in 1998.[1082] The data in the above table show a doubling in the number of notifications of dangerous consumer products between 1996 and 2000, but the number is low, even miniscule, in relation to the (admittedly unknown) total number of consumer products on the Community market. Voluntary measures or agreements were also to be notified under the RAPEX system, and these increased from zero in 1996 to 38 in 2000.

Since its introduction in 1985, there has been only one temporary measure to ban the use of a consumer product taken under Article 9 of Directive 92/59: this related to phthalates used as softeners in plastic toys and childcare articles intended for mouthing by children under three years of age.[1083] One decision has been taken to ban the marketing of laser pens in class 3 and higher of European standard EN 60825.[1084] The safety of particular tyres became an issue in 2000 following reports from the United States, and after France notified a suspension order through RAPEX the authorities and the Emergency Committee kept the position under review, but concluded that the steps taken by the manufacturer were satisfactory.[1085] ECOSA has highlighted various market surveillance issues with consumer products.[1086]

1082 *Review and Revision of Directive 92/59/EECC: Discussion Paper: Stakeholders Consultation meeting of 24 June 1999*, European Commission, 1999.

1083 OJ L315/46, 9.12.99, extended subsequently, for example C(2002) 4435, OJ L315/21, 19.11.2002. Although member state authorities maintained the public stance that this measure was relevant and justified, some have privately expressed dissatisfaction with both the mechanism that led to its being taken and some lack of substantive justification: private communications with the author.

1084 See Answer to Written Question E-0881/01, 2002/C 40 E/015, OJ C 40 E/16, 14.2.2002.

1085 Answer to Written Question E-3976/00, 2001/C 174 E/218, OJ C 174/204 and 205, 19.6.2001.

1086 Market surveillance in Finland in 1995 covered 11,900 products of which 28.5% failed to comply with regulations for marking or safety; checks on life jackets and personal buoyancy aids in Finland in 1997 revealed that 34% failed regulations and CE marking was lacking in 21%; 60 models of rattles were test purchased in Sweden in 1997 of which 30 did not pass safety requirements even though 24 of those were CE

UK Home Accident Data

The United Kingdom Department of Trade and Industry has published research on the pattern and trends in home accidents from 1982 to 1996[1087] which identifies that non-fatal injuries have been increasing (and may rise by 20% in the decade to 2010) whereas the number of deaths has consistently fallen (and may do so by 30% in this decade).

Of the almost 4,000 accidental deaths in the UK in 1996, 91% were caused by falls (50% which were also responsible for 40% of non-fatal accidents), poisoning (17%), burns (13%) and choking (5%). References occur in the statistics to faulty products or poor design being a possible cause but these are limited. Moreover, the data do not record whether the fault was due to lack of maintenance or original design. For example, Home Office fire statistics record that 89% of fires result from behavioural factors and only 11% from product faults. The DTI comment that most product fires involve cookers or space heaters and usually result because articles are placed too close. The DTI concludes that most poisoning by heating appliances is preventable if flues are cleaned regularly and equipment maintained properly.

Examples of references to products which do *not* involve defective products include falls from ladders; choking on food; asphyxiation or drowning; use of DIY products, particularly electrically powered; poisoning involving a medicine; adult or child overdoses; cutting by knives or garden equipment; scalding or burning by hot objects, particularly in the kitchen or bath or where the victim sits too close to an uncontrolled fire and falls asleep.

Even though products may not be defective or faulty, increased understanding of behaviour patterns of product use may reduce the number of accidents. For example, there has been a consistent downward trend in the accidental deaths due to electricity, with a further fall of 50% predicted from 1996 to 2010. The DTI considers that this is likely to be due to the increased use of residual current devices and general improvements in equipment design, despite the use of more and more electrical devices. Similarly, there has been a substantial decrease in non-fatal poisoning accidents involving children under 5 due to the introduction of child-resistant closures on containers.

The DTI concludes that a key area is to enable people to help themselves, such as to ensure consumers are more aware of risks in the home and how to cope with them. "Too frequently consumers underestimate the level of risk and accidents results. This can happen due to lack of

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marked: *Priorities for Consumer Safety in the European Union: Agenda for Action* (European Consumer Safety Association, 2001.

1087 *Research on the Pattern and Trends in Home Accidents* (Department of Trade and Industry, 1999). This was also the conclusion reached in USA: R D Petty, "Regulating Product Safety: The Informational Role of the U.S. Federal Trade Commission" *Journal of Consumer Policy* (1995) **18**: 387-415.

knowledge, or by an inability to see how risk can easily be reduced by small changes in behaviour". It is noted that more vulnerable groups such as older people and children feature strongly in the statistics. The DTI comments that more remains to be done in influencing behaviour. For example, the majority of falling accidents to infants and toddlers occur during normal activities such as playing and walking, and occur in living areas "where supervision can be expected to be greatest". However, it is noticeable that the DTI does not call for improvements in the level of safety of products or improvements in product design, manufacture, labelling or packaging.

UK prosecution data

These conclusions are supported by other DTI statistics that record enforcement action taken from 1988 - 1998 in relation to all consumer products[1088]. Compared with the vast number of consumer products in circulation, enforcement activity has been both stable and at a relatively low level for a considerable period. In the successive two five year periods from April 1988 to March 1993 and from April 1993 to March 1998, the total number of convictions under Part II of the Consumer Protection Act 1987 and related product-specific Regulations *fell* (1,931 to 1,588). In the earlier period, there were annual averages of 386.2 written warnings, 859 formal cautions, 340.4 suspension notices and 247.4 voluntary withdrawals of products from the market, some of which figures would overlap by relating to the same product.

Furthermore, the statistics show that most enforcement of safety regulations is restricted to particular *types* of products, such as furniture and furnishings, toys and electrical equipment. Very little enforcement activity takes place in relation to medicines[1089] or medical devices[1090].

Research report on recall of products

A DTI research report examined the number of consumer products recalled or unsafe.[1091] This stated that there had been an average of 42 consumer product recalls during the period 1990-1996 but that the figure is rising. Nearly half of these (47%) are electrical goods, followed by non-electrical toys (17%), childcare items (7%) and clothing. The main causes of these recalls are said to be potential electrical faults, including overheating, fire or electric shock, (46%) and choking by

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1088 *Consumer Safety: Report by the Secretary for Trade and Industry for the period 1 April 1988 - 31 March 1993* (HMSO 1993); *Consumer Safety: Report by the Secretary of State For Trade and Industry for the period 1 April 1993 - 31 March 1998* (HMSO 1998).

1089 There has been only one significant prosecution in relation to an advertisement for a prescription only medicine under the Medicines Act 1968: *R v Roussel* [1994] 5 Med L.R. 400.

1090 In the five years from 1994 - 1995 to 1998 - 1999 there have been issued a total of 46 Hazard notices, 172 Safety Notices but no prosecutions: Medical Devices Agency, Annual Report 1998 - 1999. This shows the regulatory emphasis is on preventive measures under a proactive post-marketing vigilance system.

1091 *Product recall research* (Department of Trade and Industry, 2000).

children (15%). Poor design was blamed in 59% of cases and manufacturing process problems in 32%.

The research report included percentages of different product types that were returned (success rates: an average of around 50% in this sample), and average costs of recalls (£39,000).

Recalls of motor vehicles in the UK are reported to be:[1092]

Year	No of campaigns	No of vehicles
2002	115	542,340
2001	178	1,724,678
2000	152	1,427,402

How many unsafe products remain unrecalled?

In a further paper[1093] the DTI tried to estimate the number and nature of potentially unsafe products that are not recalled each year in the UK but which Trading Standards Departments (TSDs) feel should be. They recognise that this is a very ambitious and complex issue, involving making speculative assumptions. It estimated, however, that around 35 product recalls fail to be made each year that should be made. However, it was reported that TSDs consider that unrecalled unsafe products are principally cheap electrical products or toys that are imported into the EU by small or medium companies, typically from the Far East.[1094]

The paper recorded that in most cases, at least half the accidents, and probably at least 75% involve products that have been used for many years, accidents arise from product failure as a result of wear and tear and lack of due care and maintenance (e.g. for electric blanket fires it is over 95%), rather than faults in new products. Many accidents also involve products that were purchased second hand. Conversely, most products deemed 'unsafe' are usually identified as being unsafe within a year of being launched (often within 6 months), and nearly all products that are recalled are recalled within 2 years of entering the market, most within 6-12 months of being sold.

The paper noted that many billions of products are used by consumers. It also noted research that the number of incidents per recalled product is extremely rare, and that many suppliers recall the products before any accidents actually happen. On average suppliers receive about 5 complaints

1092 Department of Transport, Vehicles Inspectorate Vehicles Recalls database.

1093 *Unrecalled Products: A paper on the estimated safety risks* (Department of Trade and Industry, unpublished, 2000).

1094 In a survey on import surveillance, 22% of the 54% of goods checked failed safety requirements: D Baker, "Operation Frontline Felixstowe", *Trading Standards Review* (October 2000), pp 16-17.

(mostly involving potential injury that has not occurred) per product recalled (figures ranged from 0 to 25, many less than 5), with a frequency of about 0.5 actual incidents (fire or injury) per product recalled occurred. Less than 10% of these are serious fires or injuries/deaths (ie 0.05 per product recalled). Suppliers claim that they would be informed of most (75+%) of any fires or injuries. Even allowing for gross under-reporting by consumers (ie by a factor of say 10), the authors of the paper considered that it is likely that there are less than 5 actual incidents (fires/injuries - minor/severe/fatal) per product, with a maximum of 0.5 serious incidents. Hence the paper's authors said that 60 recalled products could result at worst in 30 serious incidents a year (representing 1.3% of a theoretical upper limit estimated), and that 3-5 serious incidents is probably more likely in practice.

The paper also said:

> "Discussions with Trading Standards Officers indicate that sales of unrecalled 'unsafe' products vary. Most sales volumes (where data has been recorded by TSOs) are in the range of 5,000 to 50,000 items, with the occasional product involving 100,000 items or more. It is considered extremely rare that 250,000 'unsafe' unrecalled products would be sold.
>
> An average figure of about 30-50,000 sales is considered reasonable. This suggests that the 35 unrecalled 'unsafe' products involve about 1.5m products reaching consumers. It is very difficult to provide an accurate estimate of the number of similar products sold (that do not need to be recalled) due to the diverse nature of the products recalled. However, statistics indicate that over 250 million electrical appliances, over 1 billion electrical accessories (including light bulbs), over 500 million toys, over 500 million articles of clothing and about 900m aerosols are sold annually in the UK. A figure of 2-5 billion products purchased annually is considered a reasonable estimate, and 2 billion is used for this analysis.
>
> The 1.5 million unsafe unrecalled products sold represents less than 0.1% of the 2 billion similar articles purchased annually in the UK. In order to remain extremely conservative, 10% is recommended, and is almost certainly a conservatively high estimate of the number of deaths/severe injuries caused by unsafe unrecalled products. Hence the 35 unrecalled 'unsafe' products probably result in no more than 10% of the theoretical upper limit estimate of 940 serious fires, 70 deaths and 1215 serious injuries. Accordingly, it is estimated that the 35 unrecalled products might result in 94 serious fires, 7 fatal injuries and 121 serious injuries a year in the UK."

The paper carried out some cross-checks on these figures. The Home Office statistics record 26,000 fires annually involving electrical appliances, of which only 21% are recorded as due to faults in appliance/leads but 79% are due to misuse/consumers' actions. The 21% attributable to product faults in fact result in no more than 540 severe fires, 68 severe injuries and 22 fatal injuries. This 21% presumably largely comprises products that have become faulty as a result of wear and tear or misuse.

Similar estimates are made for events involving unsafe products (whether recalled or not), based on other research reports, as shown in Table 2.10:

Table 2.10: UK injury estimates

	fatal	non-fatal
Electric shock HADD/HASS 1991-95	6	123
DTI report on choking hazards for children, 1996 - toys/childcare items - detachable: items	2 0.4	65 20
DTI report on fatal trappings, 1996 - toys/childcare items - beds	0.5 2.2	12 55
DTI report on clothing flammability accidents, 1994	5.2	11
DTI report on strangulations by clothing, 1996	1.5	37
Total	17.8	323

Counterfeit products

In considering safety statistics, it should be remembered that they may be affected by the phenomenon of counterfeiting, which entails deliberate deception as to the quality of the product, which may involve indifference to its safety. According to the Commission, counterfeiting and piracy account for between 5% and 7% of world trade[1095] and has major repercussions in terms of consumer protection, especially as regards public health and safety.[1096]

1095 Counterfeiting Intelligence Bureau, *Countering Counterfeiting. A guide to protecting and enforcing intellectual property rights*, (International Chamber of Commerce, 1997).

1096 Green Paper: Combating Counterfeiting and Piracy in the Single Market, COM (98) 569 final, 15.10.98.

The Community's policy is specifically aimed at policing external frontiers so as to keep out counterfeit and pirated goods.[1097] The industries hardest hit at world level are listed as data processing (35%), audio-visual (25%), toy (12%), perfume (10%), pharmaceutical (6%), clock and watch (5%), phonographic and motor industries. It has been estimated that counterfeiting as a percentage of world trade rose by over 100% in value terms from 3.6% in 1990 to 5.6% in 1995.[1098] The European Commission has estimated that the shares of counterfeiting as percentages of legitimate trade in the internal market are in Table 2.11:[1099]

Table 2.11: Counterfeit goods as percentages of trade in goods in sectors

Sectors concerned	**Counterfeiting/piracy rate**
Software	39%
Audio-visual	16%
Textile	10 to 16%
Music	10%
Car spare parts	5 to 10%
Sport and leisure	5 to 7%

One respondent to the Commission's 1998 Green Paper set out statistics of counterfeit goods seized over a period in the UK: Table 2.12.[1100]

Table 2.12: Counterfeit goods seized in UK

UK	**Items**	**Value**	**Genuine Article**
Audio	216,000	£2.74m	£3.1m
Clothing	486,000	£6.3m	£14.4m
Computer & Media	34,000	£282,000	£17m
Perfume	51,000	£514,000	£1.3m

1097 Proposal for a Council Regulation concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights COM(2003) 20, 20.01.2003 aims to improve the protection measures of Regulation (EC) 3295/94.

1098 *Countering Counterfeiting. A guide to protecting and enforcing intellectual property rights*, Counterfeiting Intelligence Bureau, International Chamber of Commerce, 1997.

1099 Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee: Follow-up to the Green Paper on combating counterfeiting and piracy in the single market, COM(2000)789, 17.11.2000.

1100 Report on responses to the European Commission Green Paper on Counterfeiting and Piracy, 1999.

Sunglasses	1,100	£6,500	£45,000
Video media	28,000	£308,000	£809,000
Watches	3,000	£31,000	£213,000
Other	911,000	£19m	£40m

The Commission noted the dangers for consumers in counterfeiting goods as including unsafe toys, pharmaceuticals and medical equipment; washing powder containing caustic materials, washing powder containing caustic materials, dilution of antibiotics, carcinogenic chemicals in clothes, low grade car oil, faulty aviation replacement parts, toxic alcoholic drinks, faulty household electrical goods, ineffective anti-rabies vaccine for dogs, and faulty diesel filters.

Conclusion

Is product safety influenced more by manufacturers or by human behaviour and the use to which products are put? Conclusions, albeit unsubstantiated by data, are that behavioural factors are in fact significant in Europe. The Economic and Social Committee has said:

> "accidents ... are frequently due as much to human behaviour and ignorance as they are to dangerous products and inadequate instructions for use ...
>
> The Committee emphasises that it is the collection and analysis of facts which lead increasingly, inter alia, to the identification of unsafe products. It recognises that a product can be dangerous because it is badly designed or made, or because instructions are inadequate or incomplete; but it also points out that human behaviour, often unpredictable, is a frequent contributor to accidents."[1101]

and

> "An accident results from a product, a situation and a person - seldom from a product alone."[1102]

Similarly, the United Kingdom Department of Trade and Industry has concluded that "human behaviour seems to be the most common immediate cause of home accidents, with faulty products and poor design having an ever decreasing influence".[1103]

The somewhat limited statistical evidence points to the conclusion that products produced within the EU have a reasonably consistent level of safety and are not a major cause of accidents, but recall data indicate that imported products are of concern.

1101. Opinion on the general safety requirement for products, OJ No.C 175/12, 4.7.88.

1102. Opinion on the proposal for a Council Directive concerning general product safety, OJ No.C 75/1, 26.3.90.

1103 *Research on the Pattern and Trends in Home Accidents* (Department of Trade and Industry, 1999).

APPENDIX 3: STATISTICS ON MEDICINAL PRODUCTS

Numbers of medicinal products used

No figures are available for the total number of medicinal products placed on the market or used in the Community, save for estimates of their total monetary value. In the United Kingdom in 2001 nearly 600 million prescriptions for medicines were dispensed and some 700 million packages of non-prescription medicines were supplied.[1104]

Numbers of medicinal products authorised

Numbers of applications for and grant of marketing authorisations for medicinal products under the centralised system are given in Table 3.1 and under the mutual recognition procedure in Table 3.2.[1105] Reliable data is unavailable for the numbers of products authorised by individual member states or the total number of products on the market.

Table 3.1 : Results of the centralised procedure, February 1995 to January 2000

Total applications	245
CPMP opinions	134
Community marketing authorisations granted	118
Variations	759
Scientific advice given	142

Table 3.2: Results of the mutual recognition procedure, 1995 to 2000

Finalised procedures	650
Arbitrations on applications for marketing authorisations	6
Variations	1952
Arbitrations on variations	8

1104 National Audit Office, *Safety, quality, efficacy: regulating medicines in the UK*, (The Stationery Office, 2003).

1105 Data from the EMEA's website http://pharmacos.eudra.org/F2/pharmacos/docs.htm, quoted by A Cuvillier, "The role of the European Medicines Evaluation Agency in the harmonisation of pharmaceutical regulation", in R Goldberg and J Lonbay (eds), *Pharmaceutical Medicine, Biotechnology, and European Law*, (Cambridge, 2000).

As an indication of national licensing activity, the United Kingdom authorised an average of 1264 medicinal products a year in the period 1993/94 to 1997/98.[1106] Figures were not released for numbers of products withdrawn.

Does the introduction or existence of safety regulation contribute to an effective pre-marketing barrier in product approval? European data on this issue is difficult to access. Approval rates fell for authorisation of new drug applications in the USA as regulation increased from the 1960s to the mid 1980s, but since then has increased, as shown in Table 3.3.

Table 3.3: Percentage of new drug applications (NDAs) approved by period of submission[1107]

Period of NDA submission	Percentage of NDAs approved
1963-69	94.6
1970-74	88.5
1975-79	88.5
1980-84	76.2
1985-89	78.9
1990-94	86.1

Incidence of drug-related injuries

It is reported that about 20% of new drugs will fail because of safety concerns.[1108] Studies have reported an incidence of adverse drug reactions involving marketed drugs in the range of 10-20%.[1109] A number of smaller studies in paediatric inpatient, psychiatric and surgical wards have shown a lower incidence, perhaps, comments O'Grady, because the severity of the illness causing admission

1106 Letter from Medicines Control Agency, 10 March 1999.

1107 J A DiMasi "New drug development in the United States from 1963 to 1999", *Clin Pharmacol Ther* 2001;69:286-96.

1108 J A DiMasi, "Risks in new drug development: approval success rates for investigational drugs", *Clin Pharmacol Ther*, 2001;69:297-307.

1109 LG Seidl, GF Thornton and LE Cluff, "Epidemiological studies of adverse drug reactions", *Am J Public Health*, 65 (1965), 1170; P Gardner and LJ Watson, "Adverse drug reactions: a pharmacist-based monitoring system", *Clin Pharmacol Ther*, 2 (1970), 802. In 2001/02 the United Kingdom Medicines Control Agency evaluated 19,254 spontaneous adverse event reports, of which 3% were fatal and 57% serious, and also received 39,965 reports of adverse events occurring outside the UK, in all amounting to 384 signals of possible drug safety hazards, which lead to 51 variations to marketing authorisations: Anon, *Annual Report and Accounts 2001/02*, (Medicines Control Agency, 2002).

was less than that for medical inpatients.[1110] Studies give a death rate caused by drug treatment of 2 per 10,000 in surgical patients and 9 per 10,000 in medical patients.[1111]

Less data is available in relation to outpatients. An incidence of around 30% has been described in patients leaving hospital and followed up for 6 months.[1112] Adverse drug reactions have been reported as being responsible for around 4% of hospital admissions,[1113] one in every 40 outpatient consultations has been recorded as attributable to a drug reaction[1114] and around 40% of patients receiving drug treatment have been reported as developing some type of reaction.[1115]

A total of over 438,000 adverse drug reaction reports had been entered into the UK Adverse Reactions Register since its initiation in 1964 until 2000[1116]. These are shown in Table 3.4. The UK competent authority received some 33,000 reports of possible suspected adverse drug reactions in 2000, although with no formal assessment of causation. After assessment of causation, the UK Agency considered that it had reviewed 384 signals in 2001-02.[1117]

Table 3.4: Annual number of total and fatal adverse reaction reports to the CSM

Year	Total ADR reports	Total deaths	Fatal reaction as % of total ADR reports
1964	1415	86	6.1
1965	3987	169	4.2
1966	2386	152	6.4
1967	3503	198	5.7
1968	3486	213	6.1
1969	4306	271	6.3
1970	3563	196	5.5

1110 Quoted by J O'Grady, "Drug induced injury", in J O'Grady et al, *Medicines, Medical devices and The Law*, (Greenwich Medical Media Ltd, 1999), footnotes 8-11..

1111 Armstrong *et al.*, Fatal drug reactions in patients admitted to surgical services. *Am J Surg* 132 (1976) 643; Shapiro S, Slone D, Lewis GP and Jick H, Fatal drug reactions among medical inpatients. *J Am Med Assoc* 216 (1971), 467; Caranasos GJ, May FE, Stewart RB and Cluff LE, Drug associated deaths of medical inpatients. *Arch Intern Med* 136 (1976), 872; Porter J and Jick H, Drug-related deaths among medical inpatients. *J Am Med Assoc* 237 (1977), 879.

1112 Kellaway GSM, Intensive monitoring for adverse drug effects in patients discharged from acute medical wards. *NZ Med J* 78 (1973), 525.

1113 Cunningham G, Dodd TRP, Grant DJ, McMurdo MET, Richards RME, Drug-related problems in elderly patients admitted to Tayside hospitals, methods for prevention and subsequent reassessment. Age and Ageing 1997;26:375-82.

1114 Mulroy R, Iatrogenic disease in general practice: its incidence and effects. *Br Med J* 2 (1973), 407.

1115 Martys CR, Adverse reactions to drugs in general practice. *Br Med J* 2 (1979(, 1194.

1116. J P Griffin, *op. cit.*

1117 National Audit Office, op cit.

1971	2851	203	7.1
1972	3638	211	5.8
1973	3619	224	6.2
1974	4815	275	5.7
1975	5052	250	4.9
1976	6490	236	2.6
1977	11255	352	3.1
1978	11873	396	3.3
1979	10881	286	2.6
1980	10179	287	2.9
1981	13032	303	2.3
1982	10922	340	3.1
1983	12689	409	3.2
1984	12163	340	2.8
1985	12652	348	2.8
1986	15527	403	2.6
1987	16431	390	2.4
1988	19022	410	2.2
1989	19246	475	2.5
1990	18084	377	2.1
1991	20272	541	2.7
1992	20161	478	2.4
1993	18078	480	2.7
1994	17556	412	2.3
1995	17748	467	2.6
1996	17109	393	2.3

1997	16637		
1998	18062		
1999	18505		
2000	33094		

Numbers of products withdrawn or otherwise subject to post-marketing action on safety grounds

The number of medicinal products withdrawn or subject to post-marketing action across the Community is not available. In the period 1995 to 2002 the EMEA reports the withdrawal of 15 centrally-authorised medicinal products. Twelve of these were voluntarily undertaken based on commercial considerations, and three products were suspended and subsequently withdrawn on safety grounds.[1118] In the same period, a further 29 products were the subject of product safety announcements.[1119]

The UK authorities regard the number of medicines that have their marketing authorisations withdrawn as low, but point to a large number of other actions that are routinely taken as part of the continuous process of safety review. Figures for actions taken in the UK in 2001-02 are shown in Table 3.5.[1120]

Table 3.5: Regulatory actions other than withdrawal of a marketing authorisation

Type of regulatory action	Number of actions in 2001-02
Variations to marketing authorisations to require the inclusion of additional warnings or restrictions on labels and leaflets	515
Automatic addition of a drug to the list of intensively monitored "black triangle" medicines	78
Articles on drug safety in the Agency publication *Current Problems in Pharmacovigilance*, sent free to all healthcare practitioners who can report adverse reactions	26
"Dear Doctor" letters containing amended prescribing advice sent by pharmaceutical companies with the	9

1118 emea.eu.int/htms/human/withdraw.
1119 emea.eu.int/htms/human/drugalert.
1120 National Audit Office, op cit.

approval of the Agency	
Refusal to renew a marketing authorisation at the five-yearly renewal date	Nil

Source: Medicines Control Agency

Twelve medicines licences were withdrawn by the United Kingdom authorities in the four year period 1997-98 to 2001-02 (see Table 3.6), which the United Kingdom's National Audit Office considers to have "remained consistently low" in comparison with over 200 new licences granted in the same period and "indicating a high level of consistency and reliability in the assessments" performed by the Agency, although it notes that the medicines that were withdrawn were prescribed for common conditions that affect a significant number of people. It would have been relevant to take the analysis further by examining the number of people who were adversely affected by the medicines that were withdrawn, but no data are available for this and it would appear difficult to extract relevant data from the official mortality and pharmacovigilance systems.

However, it is not necessarily appropriate to compare bare data on numbers of drugs approved and withdrawn. Numbers of prescriptions, quoted above, would also be relevant. More importantly, it should be borne in mind that the mere fact that any post-marketing safety action may be taken in relation to a medicine does not necessarily mean that the regulatory system, in particular the pre-marketing controls, has failed: indeed, the fact that action is taken will mean that the post-marketing controls are functioning as intended. As discussed above, the mere fact of marketing approval does not mean that a medicinal product is in fact "safe", but is only a provisional judgment that is subject to further ongoing review. Whether there may have been any pre- or post-marketing failures, whether of judgment or timing, are further questions that can only be answered after detailed inquiry in each case.

Table 3.6: Medicines withdrawn by the UK authority 1997-98 to 2001-02

Year	Number of medicines withdrawn because of safety concerns	Drug names	Prescribed for
1997-98	4 (2 were of the same class of medicine)	Troglitazone (Romazin)	Type II diabetes
		Pemoline (Volital)	Attention deficit hyperactivity disorder
		Dexfenfluramine, Fenfluramine	Obesity (appetite suppressant)
1998-99	2	Sertindole (Serdolect)	Psychosis
		Mibefradil (Posicor)	Hypertension
1999-00	3 (2 were of the same class of medicine)	Pulmonary surfactant (Alec)	Neonatal respiratory distress
		Amfepramone, Phentermine	Obesity (appetite suppressant)
2000-01	2	Cisapride (Prepulsid)	Gastroinestinal problems
		Droperidol (Droleptan)	Schizophrenia
2001-02	2	Cerivastatin (lipobay)*	Hypercholesterolaemia
		Kava-Kava*	Herbal product used for anxiety

* indicates where a company made a decision to withdraw the medicine voluntarily.

Source: Medicines Control Agency

Prepulsid was associated with 125 deaths worldwide and Lipobay was associated with 52 deaths.[1121]

1121 National Audit Office, *Safety, Quality, Efficacy: Regulating Medicines in the UK. Report by the Comptroller and Auditor General.* HC 255 Session 2002-2003, 16 January 20903.

APPENDIX 4: SAFETY STATISTICS ON ELECTRICAL PRODUCTS

Safeguard Clause notifications: The significance of electrical products

The number of notifications to the Commission under the Safeguard clause during 2000 and 2001 is given in Table 4.1.[1122] This shows that electrical products are by far the most significant in relation to safety issues, whether through their electrical or, to a lesser extent, electromagnetic aspects. Some gas appliances give cause for concern, but the statistics on almost all other categories covered are very low.

Table 4.1: Safeguard clause notifications received in 2000 and 2001

Directive	2000	2001	Directive	2000	2001
Low voltage equipment (73/23/EEC, amendment 93/68/EEC)	342	428	Civil explosives (93/15/EEC)	0	0
Simple pressure vessels (87/404/EEC, amendments 90/488/EEC and 93/68/EEC)	0	0	Medical devices (93/42/EEC, amendment 98/79/EC)	[1123]	2
Toys (88/378/EEC, amendment 93/68/EEC)	4	1	Potentially explosive atmospheres (94/9/EC)	0	0
Construction Products (89/106/EEC, amendment 93/68/EEC)	0	0	Recreational craft (94/25/EC)	0	0
Electromagnetic compatibility (89/336/EEC, amendments 92/31/EEC and 93/68/EEC)	72	73	Lifts (95/16/EC)	0	0
Machinery (98/37/EC, amendment 98/79/EC)	2	15	Pressure equipment (97/23/EC)	0	0
Personal protective equipment (89/686/EEC, amendments 93/68/EEC, 93/95/EEC and 96/58/EC)	3	3	In vitro diagnostic medical devices (98/79/EC)	0	0

1122 Consultation Document Prepared by the Directorate General for Enterprise on review of the New Approach, 2001; Communication from the Commission to the Council and the European Parliament: Enhancing the Implementation of the New Approach Directives, COM(2003) 240, 7.5.2003.

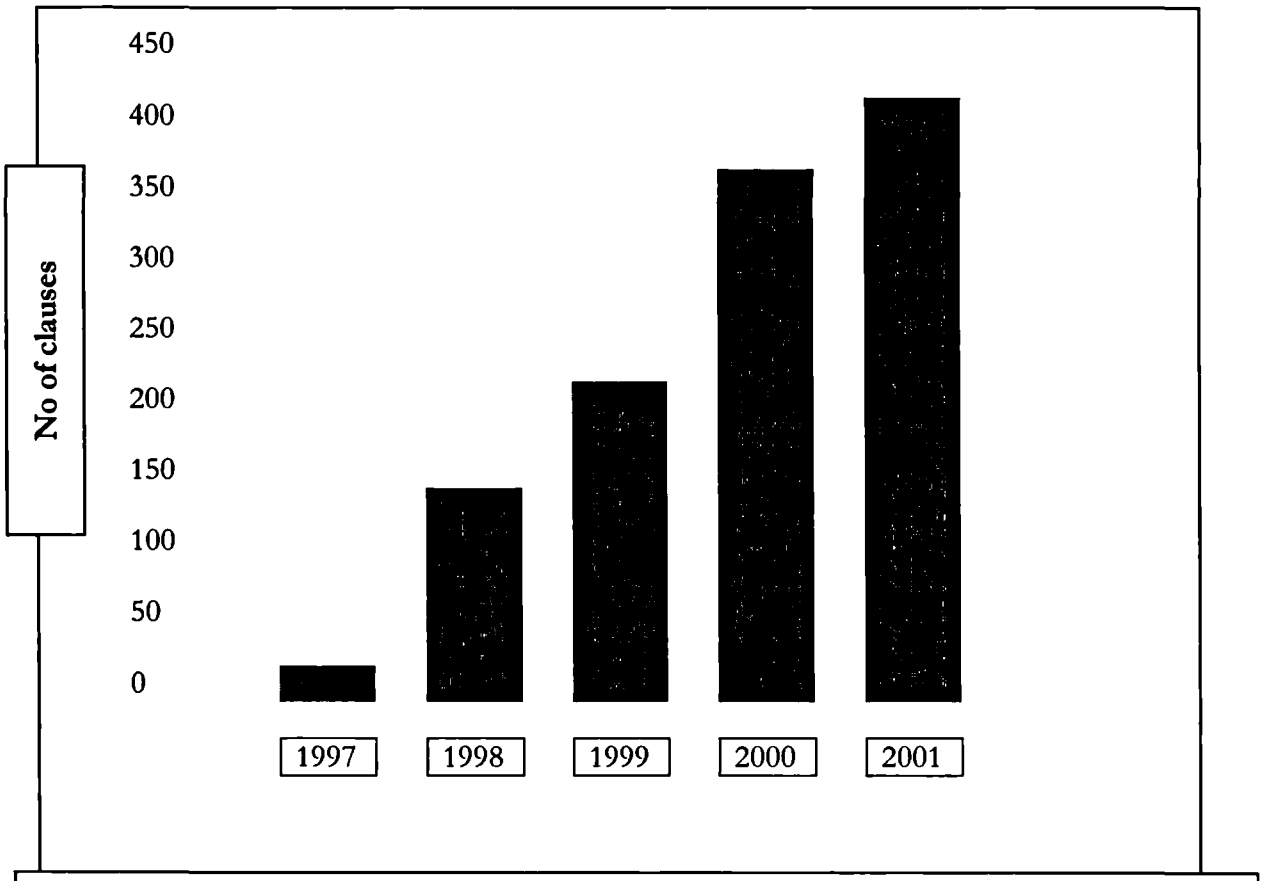
1123 Figure not stated.

Non-automatic weighing instruments (90/384/EEC, amendment 93/68/EEC)	0	0	Radio and telecommunications terminal equipment (99/5/EC)	0	0
Active implantable medical devices (90/385/EEC, amendments 93/42/EEC and 93/68/EEC)	0	0	Cableway installations designed to carry passengers (2000/9/EC)	0	0
Gas appliances (90/396/EEC, amendment 93/68/EEC)	17	7			
			Total:	**440**	**530**

The number of Safeguard clause notifications for electrical products has increased steadily over recent years, as shown in Figure 4.2,[1124] but this may be due to increased surveillance and/or reporting rather than an increase in the number of unsafe products marketed.

1124 Communication on Enhancing, *supra.*

Figure 4.2: Safeguard clause notifications - low voltage directive (73/23/EEC)

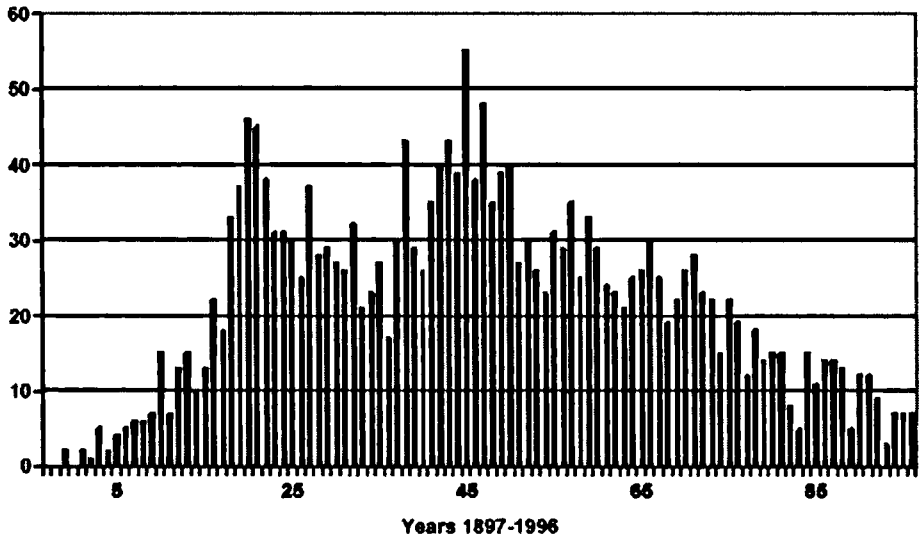


Note: the figure for 2001 corresponds to notifications received up to 1.10.2001, adjusted for a 12-month period.

The Study did not identify the number of electrical products on the Community market but noted that the main trade association, ORGALIME, represented some 100,000 companies. It did, however, quote safety statistics that were available from a number of Member States.[1125] Data from Sweden on the numbers of fatal accidents associated with electricity since records began in 1897 (Table 4.3) showed a steady fall in the late 20th century and attributed this to the existence of accreditation (now notified) bodies and to the introduction of standardisation.

Table 4.3

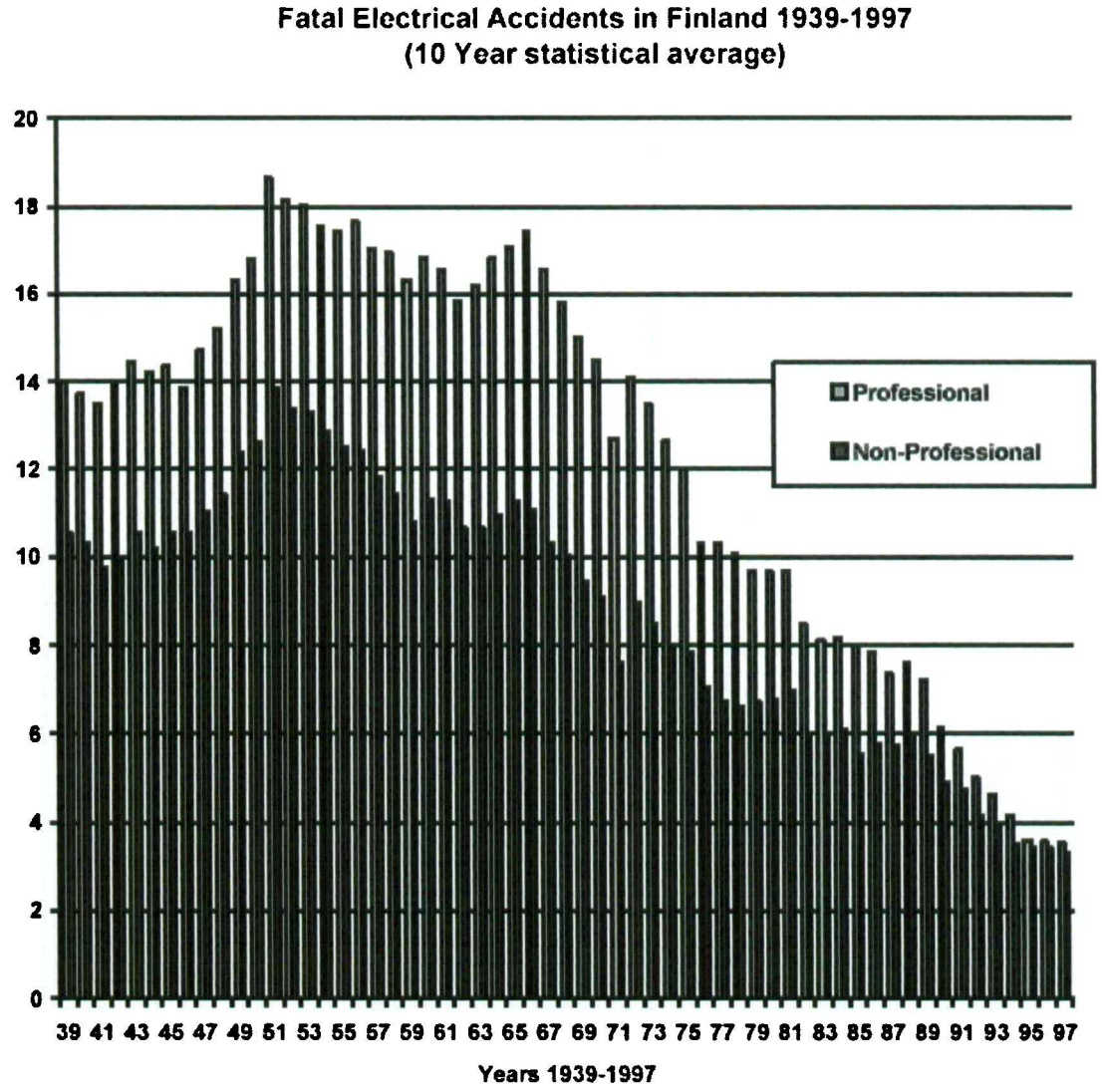
Fatal accidents associated with electricity, in Sweden (1897-1996)



1125 Ibid, sections 3 and 7.6.

The same general picture emerged from Finland: Table 4.4.

Table 4.4



However, the rise in the number of unsafe electrical products on the market during the late 1990s was illustrated by data from Finland (Table 4.5) and Austria (Table 4.6). Denmark considered that 10-15% of the products removed from the market for surveillance purposes were non-compliant and dangerous, and there was an increase in the number of prosecutions in the Netherlands in 1993-6.

Table 4.5

shown in the figure below.

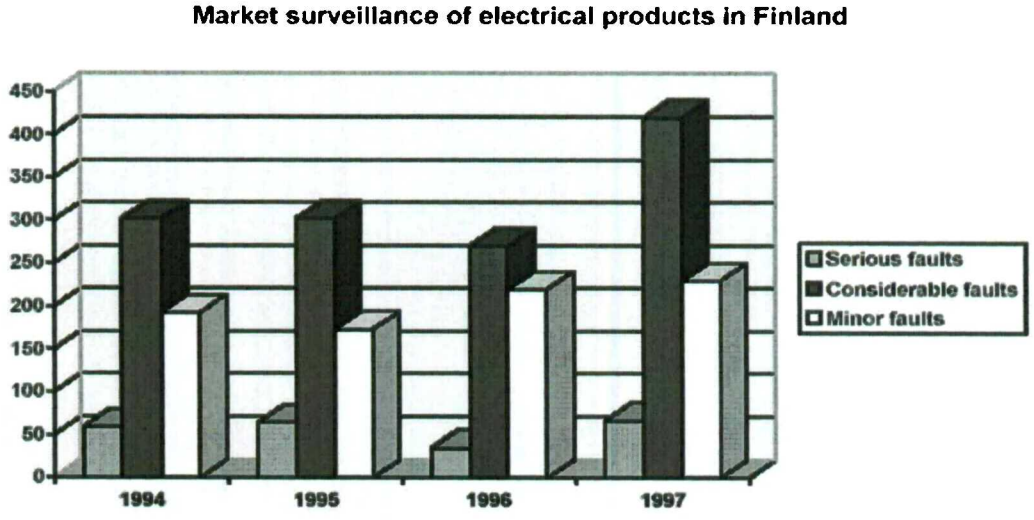


Table 4.6: Results of Austrian Market Surveillance on electrical products 1993-1997

	Supervised Companies	Investigated Electrical Products	Unsafe Electrical Products
1993	59	3800	302 (7.94%)
1994	50	3000	216 (7.20%)
1995	40	4000	135 (3.37%)
1996	31	2000	191 (9.55%)
1984-1997	694	52291	5215 (9.97%)

Fire statistics from the United Kingdom (see Table 4.7)[1126] show that accidental fires in dwellings caused by faulty appliances and leads (7,409 in 2001) were about 40% of the total of such fires caused by misuse of equipment or appliances (18,731 in 2001) and some 14% of the total number of accidental fires in dwellings (54,224).[1127] Accidental car fires have steadily declined from 25,000 in 1991 to 18,100 in 2001.

Table 4.7: Main sources of ignition for United Kingdom accidental dwelling[1128] fires, with casualties, 1999-2001

	Fires[1129]			Fatal casualties[1130]			Non-fatal casualties		
	2001	**2000**	**1999**	**2001**	**2000**	**1999**	**2001**	**2000**	**1999**
Total accidental	**54,245**	**56,684**	**58,284**	**431**	**397**	**408**	**11,649**	**12,059**	**12,555**
Smokers materials	5,473	5,277	6,083	169	168	132	2,061	2,075	2,119

1126 Source: *Fire Statistics*, Home Office, 1999-2001.

1127 Figures for earlier years are roughly the same magnitude and proportion. The average cost of commercial and domestic fires was estimated to be £63,600 and £121,500 respectively in 2001, although the cost of casualties is far higher in domestic fires: M Weiner, *Home Office Research Study 229: The economic costs of fire* (Home Office Research, Development and Statistics Directorate, 2001).

1128 Includes caravans, houseboats and other non-building structures used solely as a permanent dwelling.

1129 Including additional "late" call and heat and smoke damage only incidents.

1130 The fatality figures for 2001, 2000 and 1999 were subject to revision as later information became available.

and matches									
- Cigarette lighters	534	537	540	19	13	6	321	308	268
- Other smokers materials	4,271	4,012	4684	135	139	117	1,504	1,530	1600
- Matches	667	728	859	15	16	9	236	237	251
Cooking appliances	**30,671**	**33,880**	**34,263**	**69**	**58**	**68**	**6,191**	**6,565**	**6,945**
- Electric cookers	20,821	22,889	23,043	36	24	33	4,072	4,373	4,568
- Gas cookers	7,407	8,070	8,612	30	30	27	1,739	1,856	2,044
Space heating appliances	**2,334**	**2,405**	**2,442**	**51**	**47**	**40**	**582**	**583**	**611**
- Electric space heater	972	863	851	25	25	23	234	260	266
- Gas space heater	546	558	655	13	8	8	172	157	140
- Solid fuel: Fire in grate	343	492	494	7	9	5	71	92	91
Electrical distribution	**2,610**	**2,796**	**2,577**	**12**	**12**	**15**	**271**	**324**	**308**
- Leads to appliances	320	405		4	6		75	102	
- Wire and cable	1,936	2,103	1,942	6	5	10	167	182	192
Other electrical appliances	**5,975**	**5,629**	**6,168**	**29**	**16**	**23**	**908**	**1,019**	**1,064**
- Blanket, bedwarmer	410	421	474	11	7	12	149	157	188
- Television	611	558	602	5	4	5	179	192	218

- Candle	2,009	2,052	1,904	17	11	19	923	880	812
- Taper, lighted paper, other naked light	375	295	365	3	5	7	84	68	81
Unspecified	**865**	**639**	**730**	**73**	**74**	**94**	**247**	**207**	**201**

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EC Treaty, Articles 5, 14, 95 (ex 100a), 152 (ex 129), 153, 249.

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Directive 85/374/EEC

Directive 86/609/EEC

Directive 87/18/EEC

Directive 87/22/EEC

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Directive 88/378/EEC

Directive 89/106/EEC

Directive 89/336/EEC

Directive 89/392/EEC

Directive 89/552/EEC

Directive 89/622/EEC

Directive 89/655/EEC

Directive 89/686/EEC

Directive 90/384/EEC

Directive 90/385/EEC

Directive 91/356/EEC

Directive 91/156/EEC

Directive 91/507/EEC

Directive 92/2/EEC

Directive 92/25/EEC

Directive 92/26/EEC

Directive 92/27/EC

Directive 92/28/EC

Directive 92/41/EEC

Directive 92/59/EEC

Directive 92/73/EEC

Council Regulation 339/93/EEC

Regulation (EEC) No 2309/93

Directive 93/35/EEC

Directive 93/39/EEC

Directive 93/42/EEC

Directive 93/93/EEC

Directive 94/9/EC

Directive 94/25/EC

Regulation (EC) 3295/94

Directive 95/16/EC

Directive 95/63/EC

Directive 96/82/EC

Directive 97/23/EC

Directive 97/55/EC

Directive 98/8/EC

Directive 98/37/EC

Directive 98/43/EC

Directive 1998/79/EC

Directive 1999/5/EC

Directive 1999/34/EC

Directive 1999/44/EC

Regulation (EC) No 141/2000

Commission Regulation (EC) No 847/2000

Regulation (EC) No 2560/01

Directive 2001/20/EC

Directive 2001/37/EC

Directive 2001/63/EC

Directive 2001/83/EC

Directive 2001/95/EC

Regulation (EC) No 178/2002

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Resolution A3 - 0060/92

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